S. Hrg. 98-470

IMPROVED STANDARDS FOR LABORATORY ANIMALS

HEARING

BEFORE THE

COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY UNITED STATES SENATE

NINETY-EIGHTH CONGRESS

FIRST SESSION

ON

S. 657

A BILL TO AMEND THE ANIMAL WELFARE ACT TO ENSURE THE PROPER TREATMENT OF LABORATORY ANIMALS. (IMPROVED STANDARDS FOR LABORATORY ANIMALS ACT.)

JULY 20, 1983

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Committee on Agriculture, Nutrition, and Forestry

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IMPROVED STANDARDS FOR LABORATORY ANIMALS

WEDNESDAY, JULY 20, 1983

U.S. Senate,
Committee on Agriculture, Nutrition, and Forestry,
Washington, D.C.

The committee met, pursuant to notice, at 9:33 a.m., in room 328-A, Russell Senate Office Building, Hon. Robert Dole presiding.

Present: Senators Dole and Melcher.

STATEMENT OF HON. BOB DOLE, A U.S. SENATOR FROM KANSAS

Senator Dole. I think Senator Melcher will be along briefly, but I know he has another commitment at 10, so we will try to move as quickly as we can. This is a very important hearing, but, like many other hearings, there are always about eight or nine going on at the same time, and we would appreciate the cooperation of the witnesses in trying to summarize their statements, giving us some time for questions or comments.

It is a privilege to chair today's hearings on S. 657,[1] a bill introduced as an amendment to the Animal Welfare Act, to help insure a more humane and uniform approach to the treatment of lab animals. Senator Melcher contributed some valuable suggestions in drafting the language, and I thank him for his support.

This issue has had increasing visibility in the House and Senate over the years, and many recent legislative initiatives have produced a variety of ideas for correcting what many citizens feel are inequities in the care, treatment, and practices of using research animals.

As most of you know, at our last session I introduced S. 2948, which would have mandated research facilities to be accredited with a study to determine the costs of upgrading various structural changes. I have received comments by some who are actually involved in inspecting research facilities that we should implement such accreditation standards. My bill does not require investigation of any outside group, but instead works within the existing framework of the Animal Welfare Act. The bill does not require major expenses be invested in upgrading structural aspects of a facility.

There are a number of points I would like to address to clear up any confusion which might exist. By regulation, the Animal Welfare Act excludes birds, rats, mice, and domestic farm animals. My bill does not change these exclusions. My bill calls for no funding of alternative methods. It does ask that, where practical, such practices be considered.

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[1] See p. 168 for a reprint of S. 657.

I understand that in many situations the alternative methods have not been sufficiently developed to replace animals, yet the public does want scientists to have all possible access to alternative methods used where practical.

Our bill encourages this through the information service established at the USDA's National Agricultural Library working in cooperation with the National Library of Medicine.

The bill would also establish an animal studies committee within each institution consisting of a minimum of three people, including an outside person not related to the facility, to review ongoing care, treatment, and practices of the facility. One purpose of the committee is to assure that animal pain and distress are minimized. The committee does not have any veto power and would be chosen by the institution itself. In those cases where the institution has a large committee, several times the minimum number, it is not necessary that everyone on the committee inspect the facilities. A minimum of three, including the veterinarian and the outside member if he is available, would be sufficient for the purposes of this bill.

This bill does not call for the outside member of the committee to be an animal rights activist, but the member should be someone who is aware of the general community's concerns regarding animal welfare.

The bill does allow committee members to review the practices of the facility during experimentation; it preserves the institution's right to design their own experiments.

Following my statement I will include in the hearing record a comparison of how my bill differs from the Animal Welfare Act.

I've received letters both in support and in opposition to animal welfare legislation. A repeated comment is that although it's important to treat animals humanely, we must not impede scientific research. Indeed, humane treatment of lab animals will yield better scientific results and a greater return on the money spent for research.

I believe my bill represents a responsible and logical approach to addressing the public's legitimate concerns. It's certainly not my intent to eliminate animals from scientific research. We've only been able to discover many of the miracle cures for various diseases by using animals. However, the public's concern is that we can do a better job in caring for the animals we experiment with and minimizing their pain and distress; 19 other Senators agree with me and have cosponsored this bill.

[The comparison referred to by Senator Dole follows:]

ANALYSIS OF S. 657 AS IT AMENDS THE ANIMAL WELFARE ACT

S. 657	Animal Welfare Act
Alternatives	
Includes findings with regard to (1) New methods of testing which are faster, less expensive and more accurate than animal tests, (2) more productive use of Federal funds by minimizing unintentional duplication of animal experiments, and (3) assurance that research will continue to progress. An Animal Studies Committee must provide for annual sessions on humane practices, use of alternatives, and utilization of the information service at the National Agricultural Library to prevent unintentional duplication of animal experimentation. Requires principal investigator to give assurance that he has considered alternatives to any proposed painful procedures on animals.	Silent on alternatives.
Registration and Certification	
Certification by the Animal Studies Committee that the standards are being adhered to, including provision for adequate exercise, is added to registration and inspection under the Animal Welfare Act.	Registers research facilities and requires minimum humane handling, care, treatment and transportation standards enforced by USDA onsite visits. This applies to all facilities whether or not they receive Federal funding. Also requires registrants to keep records of each purchase or sale of live dogs and cats and to maintain identification tags for every dog and cat.
Limiting Pain and Distress	
Calls for an institutional Animal Studies Committee which must include at least one member not affiliated with the research entity who represents community concerns regarding the welfare of the animal subjects. This committee is charged, among other things, with assuring that animal pain and distress are minimized. The Secretary of Agriculture is prohibited from promulgating regulations with regard to design of research of experimentation but is authorized to issue regulations on care, treatment and practices to minimize pain and distress.	The Secretary of Agriculture is prohibited from promulgating regulations with regard to design or performance of actual research or experimentation, but is, required to issue regulations for adequate veterinary care. Registrants must submit annual reports disclosing species and number of animals used, and showing that pain-relieving drugs were used in experiments deemed to cause pain or distress.
Inspections	
In addition to existing inspection provisions, the Animal Studies Committee makes semiannual inspections; files findings with USDA and funding agencies; establishes sessions on humane practice and availability and use of alternatives. Institutions inform their employees to report to the committee any violations they observe. They will not be discriminated against for such reporting.	Veterinary inspectors from USDA Animal and Plant Health Inspection Service inspect registered research facilities.
Penalties	
In those cases where the sponsoring Federal agency determines that conditions of animal care, treatment or use in a particular project have been persistently unacceptable despite notification to the research entity, that agency shall suspend or revoke Federal support for the project.	No provision for revoking funding. Violation by a research facility of any provision of the act is punishable by a fine of up to $1,000. USDA may also impose cease-and desist order, violation of which is punishable by fines of $500 for each day violation continues.
Federal Agencies	
Laboratories of Federal agencies are included with other research facilities for inspection and compliance with the requirements of this act.	USDA receives an annual written assurance from each Federal agency that it complies with the standards.

ANALYSIS OF S. 657 AS IT AMENDS THE ANIMAL WELFARE ACT—Continued

S. 657	Animal Welfare Act
Animals Included	
Animals refers to any living warm-blooded animals, that is, birds and mammals, designated by the Secretary of Agriculture.	Same.
Exempts animals used or intended for use as food or fiber.	Same.
Conditions for Federal Grants	
No Federal money can be awarded unless the proposal includes: In its justification of the research, the details of any anticipated animal pain or distress and demonstrates that the principal investigator has considered possible alternatives to any such procedure. Assurances that a veterinarian has been employed in planning any protentially painful procedures. Provisions for assurances of the proper use of tranquilizers, analgesics, and anesthetics, and against use of paralytics without adequate anesthesia, and for appropriate pre- and post-surgical medical and nursing care; and appropriate assurances that the withholding of tranquilizers, anesthesia, analgesia, or euthanasia when scientifically necessary shall continue for only the necessary period of time. Assurances no animal shall be used in more than one major operative procedure from which it is allowed to recover except on cases of scientific necessity or special circumstances determined by the Animal Studies Committee.	None.
Waiver	
The Secretary may waive the standards under exceptional circumstances.	No waivers.

Senator DOLE. We are happy to have as our first witness Bert Hawkins, Administrator, Animal and Plant Health Inspection Service, APHIS; and Dr. William F. Raub, Associate Director for Extramural Research and Training, National Institutes of Health.

You may proceed in any way you wish. We would hope that you summarize the highlights of your testimony so we can move along quickly.

STATEMENT OF BERT HAWKINS, ADMINISTRATOR, ANIMAL AND PLANT HEALTH INSPECTION SERVICE, U.S. DEPARTMENT OF AGRICULTURE, ACCOMPANIED BY KENNETH HOOK, ASSOCIATE DEPUTY FOR VETERINARY SERVICES, AND RICHARD RISSLER, ASSISTANT DIRECTOR, ANIMAL HEALTH PROGRAMS

Mr. HAWKINS. Thank you, Senator.[1] I appreciate the opportunity to express the views of the Department of Agriculture on S. 657, a bill "To amend the Animal Welfare Act to insure the proper treatment of laboratory animals."

Appearing with me in the background this morning are Dr. Kenneth Hook, Associate Deputy for Veterinary Services, and Dr. Richard Rissler, Assistant Director, Animal Health Programs.

The Department of Agriculture, as you know, through the Animal and Plant Health Inspection Service, administers the Animal Welfare Act. One of the objectives of the act is to insure humane care and treatment of certain warm-blooded animals intended for use in research facilities. APHIS is responsible for the registration and inspection of approximately 3,300 research sites in the United States.

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[1] See p. 63 for the prepared statement of Mr. Hawkins.

Mr. Chairman, the bill the committee is considering today expands the definition of "research facility" to include each Federal department, agency or instrumentality. This means, of course, that the USDA would be required to register and inspect Federal laboratories.

Under current authorities, almost all State-owned or privately owned research facilities, which use animals for research, testing, or experiments must register currently with the USDA. Registration and inspection are the means of assuring that laboratory animals have the necessary veterinary care and creature comforts of adequate housing, handling, sanitation, food, water, and protection against extremes of weather and temperature during research and when transported. While Federal laboratories are not required to register with USDA, they are required to comply with the same standards of care and treatment and reporting requirements established for State-owned or privately owned research facilities. Federal agencies, through internal systems, monitor compliance of Federal laboratories. Therefore, we question the need to include Federal laboratories under the definition of "research facility."

We also question the provisions of the bill which change the requirements for standards of veterinary care and creature comforts from "minimum" to "proper." This change would require us to develop standards considered to be proper for the different segments of the industry and various animal species covered by the act. The term "proper" would have to be qualified, that is, proper requirements with respect to the type of animal, the species, the use of the animal, its immediate environment, and other factors. The term "minimum," on the other hand, is more definitive and more enforceable in a court of law. In practice, requirements for proper care and treatment of animals used for purposes of research, exhibition, transportation, and so forth, can be met under current authorities.

Further, we do not favor adding "adequate exercise" as a required standard because it would be extremely difficult to determine what amount of exercise would be adequate for each of the various species. Our regulations now require that the primary enclosure for each animal be properly constructed and maintained to allow the animal adequate space for freedom of movement in all directions. In addition, our inspectors are required to pay special attention to animals kept in small enclosures to insure the space provided meets our requirements, unless the research protocol calls for restricted space.

Mr. Chairman, the law and regulations are designed to leave researchers free to conduct studies they consider necessary. However, these researchers must, wherever possible, use appropriate pain-relieving drugs during actual research or experimentation. In connection with this, research facilities and Federal laboratories must submit an annual report to the Secretary on the care and treatment of animals used in research. The report must indicate whether any painful experiments were conducted and when pain-relieving drugs were not used during painful experiments.

We believe that the determination as to whether an animal is suffering momentary pain or discomfort during actual research or experimentation should be a required element of professional judgment made by the trained doctors of veterinary medicine in charge of the research and researchers trained in other biomedical sciences. Even then, there would be a lack of uniformity concerning pain interpretation. Therefore, we object to the bill's definition of the term "direct use of conscious animals" which would require the Secretary of Agriculture to promulgate regulations establishing standards for momentary minor pain and discomfort for various animal species. Additionally, this requirement, coupled with the repeal of the prohibition against the Secretary of Agriculture regulating outlines, guidelines, or performance of actual research or experimentation by a research facility, would place the Secretary in the position of regulating research projects of other Federal agencies.

Also, the bill mandates the establishment of an institutional animal studies committee, and requires each such committee to conduct inspections at least semiannually, of all animal study areas and sites of the research facility.

Senator DOLE. I would ask you to summarize your statement.

Mr. HAWKINS. You bet, Senator.

Senator DOLE. Just make the highlights; I have read the statement, and I know what it contains.

Mr. HAWKINS. Fine, Mr. Chairman. The inspections, we feel, already provided by this Department through APHIS do many of the things that are now being required by this Senate bill. Also, we feel the bill would create unnecessary oversight procedures.

We feel our regulations and standards of animal care are enforced regularly, at the present time, through unannounced inspections of the research facilities and review of their annual reports.

Because of the additional public awareness of the animal care problem, we have sent out written instructions on conducting inspections; we have established annual training sessions and brought up all of our inspectors to standards we feel are required to enforce this Animal Welfare Act.

And finally we believe that the bill's provision for establishment of an information system on improved methods of animal experimentation at the National Agricultural Library can be achieved under current authorities.

Mr. Chairman, the Department strongly supports humane care and treatment of animals, and commends the objectives of this bill to insure humane treatment, care, and appropriate use of laboratory animals, but, for the reasons previously mentioned, we cannot recommend enactment of Senate bill 657.

Thank you very much, Mr. Chairman, for this opportunity to present these remarks from the Department of Agriculture.

Senator DOLE. If it is all right with you, Mr. Hawkins, we will hear from Dr. Raub, and then we will have some questions.

I know Senator Melcher has a 10 o'clock meeting. John, do you have a statement you want to make at this time?

Senator MELCHER. I will wait till Dr. Raub is finished.

Senator **Dole**. Fine. I would ask you to summarize your statement so we can get into some questions.[1]

STATEMENT OF WILLIAM F. RAUB, ASSOCIATE DIRECTOR FOR EXTRAMURAL RESEARCH AND TRAINING, NATIONAL INSTITUTES OF HEALTH

Dr. **Raub**. Thank you, Mr. Chairman, I appreciate this opportunity to testify about the care and use of animals in research funded by the National Institutes of Health [NIH].

As you know, Mr. Chairman, my comments today for the most part will not deal directly with S. 657. I will confine most of my remarks to selected topics that I believe will be helpful in relating S. 657, and the USDA testimony about that bill, to the specific context of biomedical research.

However, the Department of Health and Human Services [HHS] has studied the bill and, if requested by the committee, we will be pleased to submit a bill report either directly or through the USDA.

Senator **Dole**. We would like to have it directly.

Dr. **Raub**. Yes, sir. I want to emphasize at the outset, Mr. Chairman, that the NIH regards animal experimentation as both a legislative mandate and a moral imperative. Biomedical research is society's only realistic hope for significant and long-lasting improvements in human health, and we must recognize that scientists need to use laboratory animals.

Every major medical advance in this century is rooted deeply in animal experimentation, and we believe this legacy is the certain prologue for the indefinite future.

At the same time, Mr. Chairman, we feel an obligation both as stewards of public funds and as scientists to promote appropriate use and proper care of laboratory animals. For several decades, the NIH has been mindful of public concerns about animal experimentation and has made vigorous effort on behalf of animal welfare.

I will summarize those activities and then describe some recent initiatives.

The first substantive step in our award process generally is the technical merit review of research proposals, and it is at that point that our attention to the proposed use of animals begins. We provide written instructions to our reviewers and the executive secretaries—the members of our staff that manage these reviews—and we instruct applicants for research grants to furnish, as an integral part of their requests, a full description of their proposed uses of vertebrate animals

There can be no award from HHS to any institution that does not have on file with NIH an acceptable statement of assurance, signed by a senior official of the institution, committing the institution to a satisfactory program of animal care and use. We also require each institution to have an animal care committee with at least one veterinarian member to assist in meeting this commitment. A little later, I will comment further in brief on the assurance process and the animal care committees.

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[1] See p. 66 for the prepared statement of Dr. Raub.

Let me turn now to some new activities. I am pleased to report on five recent initiatives that we believe will make our traditionally strong efforts even stronger.

The first item is the memorandum of understanding signed on April 11 of this year between the Departments of Agriculture and Health and Human Services. I will provide a copy for inclusion in the record. Specifically, the Food and Drug Administration [FDA], NIH, and the USDA established through this memorandum a system for information sharing to help all three entities carry out their respective roles more effectively.

[Reprint from Federal Register, Vol. 48, No. 108, Friday, June 3, 1983]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION—[FDA 225-83-8400]

Memorandum of Understanding With the Animal and Plant Health Inspection Service and the National Institutes of Health

Agency: Food and Drug Administration.

Action: Notice.

Summary: The Food and Drug Administration (FDA) has executed a memorandum of understanding with the Animal and Plant Health Inspection Service and the National Institutes of Health. The purpose of the agreement is to maintain and enhance agency effectiveness while avoiding duplication of efforts to achieve required standards for the care and use of laboratory animals. The agreement sets forth procedures of reciprocal cooperation which will assist each agency in meeting its responsibilities in promoting proper laboratory animal care and welfare.

Effective date: The agreement was effective April 11, 1983.

For further information contact: Walter J. Kustka, Intergovernmental and Industry Affairs Staff (HFC-50). Food and Drug Administration, 5600 Fisher Lane, Rockville, MD 20857, 301-443-1583.

Supplementary information: In accordance with § 20.108(c) (21 CFR 20.108(c)) stating that all agreements between FDA and others shall be published in the Federal Register, the agency is publishing the following memorandum of understanding:

MEMORANDUM OF UNDERSTANDING AMONG THE ANIMAL AND PLANT HEALTH INSPECTION SERVICE, U.S. DEPARTMENT OF AGRICULTURE, AND THE FOOD AND DRUG ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, AND THE NATIONAL INSTITUTES OF HEALTH, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, RELATING TO LABORATORY ANIMAL CARE AND WELFARE

I. Purpose

The participating agencies share a common concern for the care and welfare of laboratory animals used in research and testing. This agreement sets forth procedures of reciprocal cooperation which will assist each agency in meeting its responsibilities in promoting proper laboratory animal care and welfare. Implementation of this agreement is intended to maintain and enhance agency effectiveness while avoiding duplication of efforts to achieve required standards for the care and use of laboratory animals.

II. Background

The Animal and Plant Health Inspection Service, USDA

Each participating agency operates under its own authority for fostering proper animal care and welfare procedure. Primary responsibility is assigned to the U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) as specified in the Animal Welfare Act and its implementing regulations (9 CFR Parts 1, 2 and 3). The USDA regulations establish standards for the humane treatment of laboratory animals and a registration procedure for identifying institutions that breed, sell, transport, hold and use such animals. Adherence to these standards is achieved primarily through voluntary compliance, although formal regulatory actions may be taken in cases of flagrant and serious noncompliance. These actions may range from the confiscation of suffering animals to the issuance of "cease and desist" orders. Compliance with the USDA regulations is monitored by an active inspection program that provides for periodic inspections by veterinary medical officers or suitably trained paraprofessionals.

Food and Drug Administration, HHS

The Food and Drug Administration (FDA) is also involved in ensuring proper procedures for the care and use of laboratory animals. The source statute is the Federal Food, Drug, and Cosmetic Act as implemented by the Good Laboratory Practice Regulations (21 CFR Part 58). These regulations establish standards for the proper conduct of nonclinical laboratory studies that include animals. Adherence to the regulations sought through voluntary compliance has been found to be effective in a majority of cases. Serious noncompliance is dealt with by procedures ranging from study rejection to laboratory disqualification. Compliance is assessed through an active program of periodic inspections carried out by trained field inspectors.

National Institutes of Health, HHS

The National Institutes of Health (NIH) implements the Animal Welfare Policy of the Public Health Service (PHS Manual Chapter 1-43 and NIH Manual Issuance 4206 and 6000-3-4.58).

Each institution which receives PHS support for research involving warm blooded laboratory animals is required to submit an acceptable assurance to NIH which commits the institution to actively promote compliance with 12 basic principles for humane care and use of laboratory animals, and with the recommendations set forth in the *Guide for the Care and Use of Laboratory Animals.* Compliance is achieved by means of (a) Review and approval of assurances; (b) site visits to institutions in response to allegations of noncompliance; (c) a program of randomly selected site visits to institutions which utilize laboratory animals—for purposes of gathering information and promoting education; and (d) a nationwide education program relating to the care and use of laboratory animals.

In addition, where NIH scientific review groups conduct on-site visits to institutions to review proposed or ongoing research projects, they are encouraged to evaluate the adequacy of the care and use of laboratory animals. Finally, all scientific review groups that review research applications for scientific merit are expected to evaluate projects for compliance with the principles stated in the NIH policy when the use of laboratory animals is proposed. Clarification of responsibilities and procedures at both the institutional and NIH levels has been set fourth by the Extramural Program Management Committee Task Force 2 on Laboratory Animals. Voluntary correction of unacceptable practices is the preferred method of achieving adherence to the policy, but possible sanctions for continued noncompliance range from the suspension or termination of support of a specific project or projects of an individual investigator to withdrawal of approval of the institution's assurance, without which the institution is ineligible to receive support for research involving laboratory animals.

Shared Concerns

Although there are necessary operational differences among the animal welfare programs of the cooperating agencies, it is clear that the agencies share a concern for the care and use of laboratory animals. Common program features include evidence of concern for the welfare of laboratory animals, the promulgation and application of established standards or policies related to animal care, the maintenance of a registry/inventory of institutions and facilities subject to agency policies and regulations, the periodic conduct of routine and directed inspections or site visits, the actions designed to promote voluntary compliance, and the authority to apply a range of sanctions when the need arises.

Interagency cooperation as to common efforts provides an excellent opportunity to achieve program benefits and facilitates program operations. By sharing a perspective on acceptable standards of laboratory animal care, the agencies present a consistent approach to the regulated entities intended to foster positive compliance attitudes.

III. Substance of Agreement

The participating agencies agree to share information of mutual concern and interest about animal care and welfare programs. To facilitate the implementation of this agreement, the cooperating agencies each agree to designate a liaison officer to serve on a standing committee that will meet at a frequency of no less than once per year. Matters for consideration are to include a review of each agency's participation in this agreement and as an assignment of progress made so that necessary modifications can be made. As appropriate, the committee will also function to deal with urgent issues and specific cases of serious noncompliance.

Specifically, the participating agencies agree to:

(1) Share information contained in the registry/inventory/listing of establishments that fall under the purview of the cooperating agencies;

(2) Send to one another, each quarter, a listing of establishments that have been inspected or site visited. This listing is to be used in order to avoid redundant evaluations of the same entities;

(3) Provide to each other information on significant adverse findings concerning animal care and welfare revealed by inspections or site visits and on follow-up actions taken;

(4) Inform each other of evidence of serious noncompliance with required standards or policies for care and use of laboratory animals (including defective assurances of compliance with PHS policies) in establishments that fall under the authority of the cooperating agencies;

(5) Request from each other comments and advice on regulatory or policy proposals involving animal care and welfare under consideration by any of the cooperating agencies; and

(6) Provide each other resource persons for scientific seminars, speeches and workshops related to animal care

IV. Liaison Officers

For the Animal and Plant Health Inspection Service: Chief Staff Veterinarian, currently Arnett Matchett, D.V.M., M.S. Animal and Plant Health Inspection Service, U.S. Department of Agriculture, 6505 Belcrest Road, Hyattsville, Maryland 20782 301-436-7835

For the Food and Drug Administration: Staff Scientist, currently Paul D. Lepore, Ph.D., Bioresearch Monitoring Staff, Food and Drug Administration, 5600 Fishers Lane, Rockville, Maryland 20857, 301-443-2390.

For the National Insititutes of Health: Director, currently Charles R. McCarthy, Ph.D. Office for Protection from Research Risks, OD, Westwood Building, Room 3A18 (after February 1983 Building 31, Room 4B09, National Institutes of Health, Bethesda, Maryland 20205, 301-496-7005.

V. Period of Agreement

This agreement becomes effective on the date of last signature and continues indefinitely. It may be modified by mutual written consent of the three parties. The agreement may be terminated by any party upon a ninety (90) day advance written notice to the other parties.

VI. Authorizing Officials

For the Animal and Plant Health Inspection Service: James O. Lee, Jr., B.S., Acting Administrator.

For the Food and Drug Administration: Arthur H. Hayes, Jr., M.D., Commissioner.

For the National Institutes of Health: James B. Wyngaarden, M.D., Director.

Approved and accepted for the Animal and Plant Health Inspection Service, U.S. Department of Agriculture: By: James O. Lee, Jr., M.S. Title: Acting Administrator, APHIS Date: April 11, 1983

Approved and accepted for the Food and Drug Administration, U.S. Department of Health and Human Services by: Arthur Hull Hayes, Jr., M.D. Title: Commissioner of Food and Drugs. Date: March 22, 1983

Approved and accepted for the National Institutes of Health, U.S. Department of Health and Human Services:

By: James B. Wyngaarden, M.D. Title: Director, NIH. Date: February 3, 1983

Effective date. This memorandum of understanding became effective April 11, 1983.

Dated: May 17, 1983.

William F. Randolph,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 83-14698 Filed 6-2-83; 8:45 am]

BILLING CODE 4160-01-M

Dr. Raub. The second activity is our ongoing effort to update and refine the NIH "Guide for the Care and Use of Laboratory Animals." First published in 1963 and antedating even the Animal Welfare Act, this publication has been acclaimed widely by veterinarians, laboratory scientists, research administrators, and lay persons alike as the most authoritative guidance of its kind. In particular, it is the cornerstone of our administrative requirements governing animal experimentation funded by NIH, and it also provides the conceptual and substantive framework for the activities of the American Association for the Accreditation of Laboratory Animal Care [AAALAC].

The Institute of Laboratory Animal Resources [ILAR] of the National Academy of Sciences now is at work under an NIH contract to revise the guide, as appropriate, building on the traditionally strong role ILAR has played in this effort. This time, at the request of NIH, the process included a series of public hearings providing for broad public comment on the current version of the guide. We are optimistic that this new dimension in the process will make an already strong guidance even stronger.

The third initiative involves a series of site visits this summer by NIH staff and advisors to a random sample of awardee institutions to assess their programs of animal care and use based on the statements of assurance I mentioned earlier. The NIH regards accreditation by AAALAC as the strongest form of assurance but recognizes that there are other acceptable forms. The assurance system operated by NIH is based on trust between the Department of Health and Human Services and its awardees. We believe it is fundamentally sound. However, in a few instances over the last several years, NIH found awardees to be out of compliance with their assurances, and we came under severe criticism for not detecting and acting upon those breaches of trust sooner. The result was a threatened erosion in public confidence in our stewardship, a prospect we found unacceptable.

We therefore undertook a formal assessment of the assurance system. After developing a detailed protocol with the help of three AAALAC-accredited institutions, we then selected a random sample of institutions for the site visits. Site visitors are NIH staff and non-Federal consultants with expertise in laboratory animal medicine and/or research.

We expect to complete the visits by October and to decide then whether and, if so, in what form, to continue this initiative. With your permission, Mr. Chairman, I will submit for the record copies of recent public announcements about these site visits.

[NIH Guide for Grants and Contracts—Vol. 12, No. 2, Feb. 25, 1983]

SITE VISITS TO ANIMAL CARE FACILITIES—NATIONAL INSTITUTES OF HEALTH

The National Institutes of Health (NIH) is embarking on a series of site visits to randomly selected awardee institutions to assess the adequacy of the current process for promoting proper care and use of animals in the biomedical research which NIH funds.

In particular, the visits are intended to determine whether or not the facilities, systems, and practices for the care and use of laboratory animals are consonant with the statements of assurance now on file with the NIH.

The information gathered will be valuable for addressing three overriding questions: Is the present assurance system adequate? Even if adequate, how can it be improved? If inadequate, what other approaches should be explored?

I. BACKGROUND

As a part of its overall mission to fund high-quality biomedical research and research training, the NIH has an obligation to promote the appropriate care and use of laboratory animals. Since 1971, the NIH has required awardee institutions which conduct experiments with laboratory animals to submit written statements of assurance committing themselves to follow the principles set forth in the NIH *Guide for the Care and Use of Laboratory Animals* as well as all federal, state and local statutes relating to laboratory animals. In addition, many institutions have sought and received accreditation by the American Association for Accreditation of Laboratory Animal Care (AAALAC).

As a matter of policy, the NIH negotiates these assurance statements carefully but has made no systematic effort to assess compliance unless concerns are raised by: (a) peer reviewers and/or staff during the normal processes of evaluating applications, proposals, and progress reports, (b) individuals or groups who submit invaluable allegations, and/or (c) authorized inspection, such as performed by the United States Department of Agriculture under the Animal Welfare Act of 1966 (as amended). In recent years, critics of NIH policies have questioned the adequacy of the assurance process both in concept and in relation to a few specific instances of actual or apparent failure by awardees to ensure appropriate practices. Because of the need to maintain public confidence in science and in the officials who administer Federal funds, the NIH has decided to examine its assurance system.

II. APPROACH

The effort is being conducted under the leadership of the Office of Extramural Research and Training (OERT). NIH staff and advisors have developed a protocol for conducting the site visits. The first group of institutions will be visited during the period March through September 1983. Visits will be made stratified, random sample of ten institutions which operate under approved assurances but which do not have accreditation from the AAALAC. The institutions will be selected according to the following plan: (a) one institution will be chosen from each of the ten Department of Health and Human Services geographic regions, and (b) three of four institutions will be taken from each of three categories of total annual NIH support of more than $10 million, $5–10 million, and less than $5 million.

Each site visit team will be composed of several members (usually 3–5), comprising NIH employees and non-federal consultants. A member of the NIH staff will notify the appropriate insitutional representative(s) about one month before the scheduled visit.

Additional information concerning this notice may be obtained from: Dr. Louis R. Sibal, Office of Extramural Research and Training, National Institutes of Health, Shannon Building, Room 314, Bethesda, Maryland 20205, Telephone: (301) 496–4716.

[NIH Guide for Grants and Contracts—Vol. 12, No. 6, June 17, 1983]

NOTICE: SITE VISITS TO ANIMAL CARE FACILITIES—NATIONAL INSTITUTES OF HEALTH

As announced in the February 25, 1983 *NIH Guide for Grants and Contracts,* the Office of Extramural Research and Training (OERT) is embarking on a series of site visits to awardee institutions to assess the adequacy of the NIH's current process for promoting proper care and use of animals in the biomedical research it funds. During January and February of this year, OERT developed a protocol for the visits and used it on three site visits to nearby institutions. The protocol includes meetings with top administrative officials, Animal Care Committee members, selected investigators and attending veterinarian(s) as well as tours of facilities. OERT is now ready to conduct site visits to ten awardee institutions to assess its current policies.

In order to assess the system presently used to ensure and promote animal welfare, OERT has randomly selected institutions which are not accredited by the American Association for Accreditation of Laboratory Animal Care (AAALAC) but which submit annual assurance statements attesting to their observance of the principles set forth in the NIH's Guide for the Care and Use of Laboratory Animals. Ten institutions were selected: one was chosen from each of the ten Department of Health and Human Services (DHHS) geographic regions, and three or four were taken from each of three categories of total annual NIH support of more than $10 million, $5–10 million, and less than $5 million. Using these criteria, OERT randomly selected the following institutions:

DHHS REGION: INSTITUTION/LOCATION

1. Brandeis University, Waltham, MA.
2. New York University, New York, NY.
3. Children's Hospital of Pittsburgh, Pittsburgh, PA.
4. Bethune-Cookman College, Daytona Beach, FI

5. Northwestern University, Evanston, IL.
6. University of Texas—Austin, Austin, TX.
7. St. Louis University, St. Louis, MO.
8. LDS Hospital, Salt Lake City, UT.
9. Syntex Research Division, Palo Alto, CA.
10. University of Washington, Seattle, WA.

The ten institutions will be visited between June and September of this year by site visit teams composed of NIH employees and non-federal consultants. A member of the NIH staff will have notified the appropriate institutional representative(s) at least one month before the scheduled visit.

Additional information concerning this notice may be obtained from: Dr. Louis R. Sibal, Office of Extramural Research and Training, National Institutes of Health, Shannon Building, Room 314, Bethesda, Maryland 20205, Telephone: (301) 496-4716.

Dr. RAUB. My fourth example relates in part to S. 657, namely, that part which deals with the composition and functions of animal care committees within awardee institutions. Recently, we have been exploring the nature and extent of additional guidance that might be appropriate with respect to these local committees. In particular, we believe there is considerable merit in the notion that the committees might include at least one nonscientist member and at least one individual not employed by the institution. We plan to seek comment from the scientific community and the general public on these and related matters during the coming fiscal year.

Finally, I call to your attention a special effort to identify nonanimal research methods that are deserving of further development and evaluation. I am referring specifically to the plans of our Division of Research Resources [DRR] to sponsor a series of workshops focused on biological systems such as mammalian cell culture, invertebrates, and micro-organisms and on physical science techniques such as mathematical modeling and computer simulation. To the extent that DRR can identify new research and development opportunities in this area and foster the emergence of new concepts and methods, it ultimately could reduce our dependency on laboratory animals.

That concludes my report, Mr. Chairman. I will be glad to respond as best I can to any questions the committee may have.

Senator DOLE. Thank you very much. I want again to recognize the presence of Senator Melcher who is the real expert in this area, and it is our bill that is under consideration. However, I want to indicate it is not just the two of us; there are six original cosponsors including: Senator Melcher, Senator Randolph, Senator Heinz, Senator Percy, Senator Stevens, and myself. And since that time there have been 14 additional sponsors.

So this is a serious matter, and there is strong support for it. We hope we can address some of the real concerns that may be raised. I yield to Senator Melcher.

STATEMENT OF HON. JOHN MELCHER, A U.S. SENATOR FROM MONTANA

Senator MELCHER. Thank you, Mr. Chairman. I am convinced that there can be improvements made in the Animal Welfare Act.

The question of facilities always comes up. The standards have been minimum standards. What that means, first of all, is the interpretation of the Department; second, the research facility; and third, Congress. I don't think we knew exactly what we were talk-ing about when we said minimum standards in facilities would be provided.

I am not sure I know what proper standards would be either. But I think the intent is clear. I think the intent—and it is not just the intent of Congress, I think it is the intent of the public that these facilities be made very clean, and very adequate in size. We should think of what we would want as individuals, and what animals would want, too, in the way of facilities and comfort.

I think we can do a better job on what proper facilities are, and I think it is time we upgrade from whatever minimum standards are.

I am very much interested, and I gather everybody is, in finding ways of accomplishing the same goals in research without inflicting pain or death on animals—that is exactly what we want to do. We can look at what incentives are possible and should not be too reluctant to do so.

Third, on these guidance committees, I am pleased at what you said about NIH—I think it's very good. I think we can improve on that, and this bill certainly intends to do that.

One of the things we have to be sure of is that the Department of Agriculture wants that responsibility, because if the Department of Agriculture doesn't want that responsibility, then I have a problem with the Department of Agriculture. There has been some indication over the past several years that the Department of Agriculture really doesn't enjoy that responsibility. I don't care whether the Department enjoys it or not; if we give it that responsibility, it had better welcome it and it better do a bang-up job with it. One of the criticisms we have had is that there really hasn't been any inspection.

It is a little bit frustrating to have the Secretary of Agriculture and people down at OMB look down their noses about putting enough money in the budget to operate this program under the Animal Welfare Act. That isn't what the public wants, that isn't what the taxpayers want. After all, this is a very minuscule amount of money.

NIH is awarding all these grants. Certainly a lot of money has been made available even under this administration, which has been working with Congress to cut expenses. There has been money available for NIH and all the research grants. I think animal welfare is part of the cost of those grants. If you impose standards that are better and more humane, a great share of those costs are going to be paid out of those grants.

I am not really satisfied with this bill; I don't suspect any of the sponsors are really satisfied with it yet. The testimony today is going to be most helpful. I am not satisfied with the way it hangs together. I am not satisfied with some of the language in it. I don't want to go toward the end of the spectrum which would make it more loose; I go toward the end of the spectrum that makes it more tight.

One of the things we have got going for us in a bill like this, as has been the case here the last 10 years, is that Christine Stevens has started to coordinate and expedite all the various groups that are affected by this bill. We are obliged for that help; we want to utilize it, because I think that through her efforts and the people with whom she deals directly, and she deals with so many of them, it's a whole spectrum that has been involved—that we have the opportunity to pass the bill.

My concern is that we pass a good bill, a solid bill, and I know that NIH and the Department of Agriculture can help in that regard. I want to go for tightening it up, not loosening it up.

Thank you, Mr. Chairman.

Senator DOLE. Thank you, Senator. Again I want to thank Senator Melcher, and we will be working together trying to move this bill forward, whether it's in the present form or a rewritten form or a modified form.

Sometimes we are so busy with other things around here we fail to address some real concerns that may not seem important to some people, but they really are important. Congress talks about deficits and a lot of things that animals don't worry much about—but Senator Melcher wouldn't be here and I wouldn't be here—it's not a media event, if it weren't a serious concern. I want to underscore what he said about Christine Stevens. She has been very helpful to us and we appreciate her support in developing responsible legislation.

So we are not here to quarrel with NIH or APHIS; we are here to try to figure out what we can do to accomplish the things Senator Melcher just addressed so eloquently.

For the record, Mr. Hawkins, how often does your current level of funding allow you to inspect registered research facilities?

Mr. HAWKINS. Senator, some facilities, of course, are inspected biannually and others three times and some more than that; we try to conduct inspections at least two and a half times annually of all these facilities.

Senator DOLE. Would it be helpful to have inspections by animal study committees to supplement your own inspections?

Mr. HAWKINS. Senator, as the testimony indicated, we feel that trained veterinarians who are dealing all the time with animals and animal care are better trained to make these observations as to facilities and their condition than committees might be

Senator DOLE. If that is the case, would it be helpful to the inspecting veterinarians to be able to review practices during experimentation rather than relying on existing authority for determining whether pain-relieving drugs are used?

Mr. HAWKINS. Senator, if I might, I would like to refer that question to Dr. Rissler, my veterinarian associate who is more particularly involved in the adjudication of this.

Dr. RISSLER. About two-thirds of the facilities that are presently registered do have animal care committees functioning now, and we do have access to protocols and this type thing that are affecting veterinarians; if there seems to be a need, we can look at the protocols through these committees at the present time

Senator MELCHER. Could I ask the doctor a question?

Senator DOLE. Sure.

Senator MELCHER. Doctor, I think the point of the question is: Does consultation by the inspector with the committees prove helpful?

Dr. RISSLER. In certain instances, yes, and I have no doubt it has in the past.

Senator MELCHER. It would be good if you could identify what it is about those committees that proved helpful. I think there is a difference in makeup of the committees and how they operate, and if you have found committees that are helpful, I think that is exactly what Senator Dole and I are looking for, to see how they formed those committees and what is their makeup.

I think what we are after in the bill is to get specific guidance from the committees who are there routinely all through the year, or who meet routinely.

Senator DOLE. Dr. Raub, in the past has NIH been checking to see if animal care committees have been conducting investigations?

Dr. RAUB. The only checking we have done, Mr. Chairman, is in those instances where we either were in receipt of allegations about potential failings of the programs within the institution or where we had other reasons to believe that that might be the case. We have carried out some site visits and have, among other things, interviewed members of the animal care committees during those visits. But with the exception of specific allegations or other reasons to be concerned, we have not routinely made such visits.

The series of random site visits that I mentioned briefly in my testimony is an attempt to go beyond responding to particular situations to provide a more systematic and better balanced sample of the nature and the extent of the animal care programs, including the functions of the animal care committees.

Senator DOLE. Do you have a record of the number of checks you have made?

Dr. RAUB. It is a very small number, Senator; I don't have the number offhand, but we could certainly supply that to you.

[The following information was subsequently received by the committee:]

Since September 1981, the NIH Office for Protection from Research Risks [OPRR] has conducted five investigations of allegations of noncompliance with applicable Public Health Service [PHS] policy and NIH guidelines governing the care and use of laboratory animals. In four of the five investigations the allegations were made known to OPRR by individuals who were not directly associated with the laboratory facility or the research being conducted. In three instances onsite visits by Federal and non-Federal representatives were carried out as part of the investigation. Two investigations yielded no evidence of noncompliance with the PHS policy. In two cases, deficiencies were found and corrective measures undertaken by the institutions involved. In the remaining case evidence led to the conclusion that there was material failure to comply with the PHS policy, and the grant was terminated. Complete records of the investigations are available from OPRR.

Senator DOLE. Are institutional review boards for human experimentation set up in a way that prevents the leakage of confidential information?

Dr. RAUB. There are such safeguards, generally taking the form of education and admonitions to the members of the committees with respect to concerns about proprietary information or other information that should be regarded as confidential. That has worked well in the human subjects area, and we have no cause to believe that there are different reasons to be concerned with respect to the care and use of lab animals.

Senator DOLE. Do you have a list of the institutions who have animal care committees?

Dr. RAUB. Yes, sir.

Senator DOLE. Which would indicate you also have a list of those who do not have committees.

Dr. RAUB. We require the existence of an animal care committee as part of an acceptable assurance. Therefore, of the approximately 700 institutions that are authorized to use HHS funds for animal experimentation, every one of them has an animal care committee.

Senator DOLE. Well, you might supply those for the record if there are some who do not have committees.

Dr. RAUB. Yes, sir.

[The following material was subsequently received by the committee:]

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
National Institutes of Health
Bethesda, Maryland 20205

January 7, 1983

AMINAL WELFARE
SEVENTH CUMULATIVE LIST OF INSTITUTIONS WITH AN APPROVED ANIMAL CARE ASSURANCE

(This list is issued as required by PHS "Grants Administration Manual," Chapter 1-43, Section 1-43-50, Oct. 27, 1978.)

The institutions listed have acknowledged the use of warm-blooded animals (land and water mammals and birds) in activities supported by PHS grants, contracts, or awards, and have provided the Office for Protection from Research Risks (OPRR), OD, NIH, with acceptable written assurance statements, as required by Section 1-43-20 of the policy.

****

SPECIAL ATTENTION IS NEEDED TO ASSURE HUMANE USE OF ANIMALS AND EFFECTIVE APPLICATION OF PHS POLICY. INCREASED PUBLIC CONCERNS HAVE RECENTLY LED TO COMPLAINTS, CAMPAIGNS, DEMONSTRATIONS AND OTHER ADVERSE ACTIVITIES AGAINST GRANTEES, CONTRACTORS, AND AWARDING AGENCIES.

****

GRANTS involving the use of animals:

RESPONSIBILITY OF INITIAL REVIEW GROUP STAFF:

1. Please identify the species in all types of summary statements (research, career, fellowship, training) after the last sentence of the "Description" or "Research Plan."

2. For proposals which raise questions about humane procedures, proper care and/or facilities, please use "Special Note," e.g., "Animal Subjects - Questionable Procedures" or "Animal Welfare" and identify concern(s) in a labeled paragraph after Critique.

3. For proposals presenting no animal concerns, please provide a simple statement to that effect at the end of the Critique.

RESPONSIBILITY OF AWARDING PROGRAM STAFF:

1. Please verify the use of warm-blooded animals.

2. Please verify that grantee institution appears on this list and that animal concerns have been resolved.

3. If grantee institution (and/or any performance site involving animals) is not on the list, if an award is likely to be made after any animal concerns have been resolved, please forward a copy of the title page of the proposal (with species noted) to OPRR, with request that an assurance be negotiated.

   No award is to be made until program staff have been notified by OPRR that an assurance has been accepted.

CONTRACTS AND OTHER AWARDS: See next page

CONTRACTS AND OTHER AWARDS:

1. Please verify the use of warm-blooded animals.

2. Please verify that contractor or awardee institution appears on this list and that animal concerns have been resolved.

3. If contractor or awardee institution (and/or any performance site involving animals) is not on the list, if an award is likely to be made after any animal concerns have been resolved, please forward to OPRR a memorandum identifying the proposal, the institution, and the institution's responsible official and address, with the request that an assurance be negotiated.

   No award is to be made until the contracting officer or other requestor has been notified by OPRR that an assurance has been accepted.

ALL PROPOSALS involving the use of animals:

Proposals which raise questions during review should be identified by a memorandum to OPRR, with copies of awarding program's action if any) or a statement of planned action.

Descriptions of the required actions are in Sections 1-43-50B and 1-43-50C of the PHS manual chapter and Sections 4206 and 6000-3-4.58 of the NIH manual.

In general, OPRR, OD, NIH, is responsible for monitoring institutional compliance with the policy and therefore must be kept informed. Operating agency staff must determine that individual projects conform to requirements. However, significant noncompliance would require further action by OPRR.

Inquiries about the list or policy should be directed to Mrs. Helen Gordon, Animal Welfare Officer, Westwood Building, Room 3A12 (Building 31, Room 4B-25 after February 1983), telephone 301 496-7041.

INSTITUTIONS WITH AN APPROVED ANIMAL CARE ASSURANCE AS OF JANUARY 1983

ASSURANCE NUMBER	STATE/INSTITUTION	ASSURANCE STATUS	CITY
	ALABAMA		
A0701	Alabama, University of..................................		Birmingham
A2098			Huntsville
A1429			University
A0955	Carver Research Foundation of Tuskegee Institute........		Tuskegee Institute
A3005	Selma University..		Selma
A1631	South Alabama, University of, College of Medicine.......		Mobile
A0002	Southern Research Institute.............................		Birmingham
A0955	Tuskegee Institute, Carver Research Foundation of.......		Tuskegee Institute
	ALASKA		
A1632	Alaska, University of...................................		Fairbanks
	ARIZONA		
A0433	Arizona State University................................		Tempe
A1380	Arizona, University of..................................		Tucson
A1380	College of Medicine		
A2007	Barrow Neurological Institute (St.Joseph's Hosp/Med Ctr)		Phoenix
A2007	St. Joseph's Hospital and Medical Center................		Phoenix
A0343	Veterans Administration Hospital........................		Tucson
	ARKANSAS		
A2077	Arkansas State University...............................		State University
A1482	Arkansas, University of.................................		Fayetteville
A3022			Little Rock
A2006	Veterans Administration Hospital........................		Little Rock
	CALIFORNIA		
A1823	Addiction Research Foundation...........................		Palo Alto
A1801	Alza Research...		Palo Alto
A2031	Ames Research Center/NASA...............................		Moffett Field
A1303	California Institute of Technology......................		Pasadena
A0003	California State Dept Hlth Services, Lab Services Branch		Berkeley
A2099	California State Polytechnic University, Pomona.........		Pomona
A2039	California State University Dominguez Hills.............		Carson
A0104	California State University, Fullerton..................		Fullerton
A1504	California State University, Hayward....................		Hayward

INSTITUTIONS WITH AN APPROVED ANIMAL CARE ASSURANCE AS OF JANUARY 1983

ASSURANCE NUMBER	STATE/INSTITUTION	ASSURANCE STATUS	CITY
A2062	California State University, Long Beach		Long Beach
A1723	California State University, Los Angeles		Los Angeles
A1612	California, University of, Davis		Davis
A1151	California, University of, Irvine		Irvine
A1151	California College of Medicine		
A1151	School of Biological Sciences		
A1882	California, University of, Lawrence Berkeley Laboratory		Berkeley
A1816	California, University of, Lawrence Livermore Laboratory		Livermore
A3036	California, University of, Los Alamos Natl Laboratory		(Los Alamos, NM)
A1440	California, University of, Los Angeles		Los Angeles
A1405	California, University of, Riverside		Riverside
A1555	California, University of, San Diego		La Jolla
A1234	California, University of, San Francisco		San Francisco
A0700	California, University of, Santa Barbara		Santa Barbara
A1150	California, University of, Santa Cruz		Santa Cruz
A1400	Cedars-Sinai Medical Center		Los Angeles
A3004	Center for Neurologic Study		San Diego
A1846	Charles R. Drew Postgraduate Medical School		Los Angeles
A0374	Children's Hosp Med Ctr o/No.Cal.,Bruce Lyon Mem Res Lab		Oakland
A1302	Childrens Hosp of Los Angeles		Los Angeles
A0311	City of Hope National Med Ctr & Research Institute		Duarte
A1089	Doheny Eye Fdn (Univ. of Southern California)		Los Angeles
A3017	Gladstone Fdn Labs/Cardiovascular Disease (U Cal.,S.F.)		San Francisco
A0363	Institutes of Medical Sciences		San Francisco
A2033	La Jolla Cancer Research Foundation		La Jolla
A1234	Langley Porter Neuropsych.Inst.Brain-Behav.Ctr(U Cal.SF)		Eldridge
A1882	Lawrence Berkeley Laboratory (U Cal., Berkeley)		Berkeley
A1816	Lawrence Livermore Laboratory (U Cal., Livermore)		Livermore
A2064	Linus Pauling Institute of Science and Medicine		Menlo Park
A0439	Los Angeles County Harbor-University of California Los		
A0439	Angeles Medical Center, Professional Staff Assn of		Torrance
A1089	Los Angeles County/Univ of Southern Cal Med Ctr		Los Angeles
A3044	Mary's Help Hospital & US PHS Hansen's Disease Project		Daly City
A3038	Medical Biology Institute		La Jolla
A0448	Mount St. Mary's College		Los Angeles
A2031	NASA/Ames Research Center		Moffett Field
A1519	Pacific, University of, School of Dentistry		San Francisco
A2005	Pacific, University of, School of Pharmacy		Stockton
A1749	Palo Alto Medical Research Foundation		Palo Alto
A1612	Peralta Cancer Res Inst(via U.Cal,Davis,CA 34194 only)		Oakland
A2003	Pomona College		Claremont

INSTITUTIONS WITH AN APPROVED ANIMAL CARE ASSURANCE AS OF JANUARY 1983

ASSURANCE NUMBER	STATE/INSTITUTION	ASSURANCE STATUS	CITY
A0010	Rancho Los Amigos Hospital, Professional Staff Assn of..		Downey
A0440	Salk Institute for Biological Studies		San Diego
A1812A	San Diego State University		San Diego
A1234	San Francisco General Hosp (Univ of Cal, S.F. facility).		San Francisco
A2013	San Francisco State University		San Francisco
A0122	San Jose State University		San Jose
A3013	Santa Clara, University of		Santa Clara
A0699	Scripps Clinic and Research Foundation		La Jolla
A1696	Sonoma State Hospital Brain-Behavior Res. Ctr (Langley		
A1696	Porter Neuropsychiatric Inst., U Cal., S.F.)		Eldridge
A0113	Southern California College of Optometry		Fullerton
A1089	Southern California, University of		Los Angeles
A0479	SRI International		Menlo Park
A1333	Stanford University		Stanford
A1333	School of Medicine		
A2098	Syntex Research		Palo Alto
A3018	Thoratec Laboratories Corporation		Berkeley
A0012	U.S. Public Health Service Hospital		San Francisco
A0014	Veterans Administration Hospital - Brentwood		Brentwood
A1165	Veterans Administration Hospital		Long Beach
A0014	Veterans Administration Hospital (Wadsworth)		Los Angeles
A1759	Veterans Administration Hospital		San Francisco
A0013	Veterans Administration Hospital		Sepulveda
A3031	Whittier Institute for Diabetes and Endocrinology		La Jolla
A2027	Zoological Society of San Diego		San Diego
	COLORADO		
A0015	AMC Cancer Research Center and Hospital		Lakewood
A1317	Colorado College		Colorado Springs
A0383	Colorado State University		Fort Collins
A1609	Colorado, University of, at Boulder		Boulder
A1557	Medical Center		Denver
A1709	Denver General Hospital of City/County Dept Hlth/Hosp...		Denver
A3029	Fort Lewis College		Durango
A1849A	National Asthma Center		Denver
A1621	National Jewish Hospital & Research Center		Denver
A3027	Southern Colorado, University of		Pueblo
A1458	Western State College of Colorado		Gunnison

INSTITUTIONS WITH AN APPROVED ANIMAL CARE ASSURANCE AS OF JANUARY 1983

ASSURANCE NUMBER	STATE/INSTITUTION	ASSURANCE STATUS	CITY
	CONNECTICUT		
A1267	Connecticut, University of		Storrs
A1606	Health Center		Farmington
A1318	Hartford Hospital		Hartford
A3001	Hartford, University of		West Hartford
A0016	John B. Pierce Foundation Laboratory		New Haven
A1430	New England Institute		Ridgefield
A3015	Saint Francis Hospital and Medical Center		Hartford
A1415	Trinity College		Hartford
A2065	Veterans Administration Hospital		Newington
A1445	Wesleyan University		Middletown
A0441	Yale University Faculty of Arts and Sciences		New Haven
A0441	Medical School		
	DELAWARE		
A1717	Delaware State College		Dover
A1590	Delaware, University of		Newark
	DISTRICT OF COLUMBIA		
A1560	American University		Washington
A0347	Armed Forces Institute of Pathology (Dept of Defense)...		Washington
A1195	Carnegie Institution of Washington (See Maryland)		(Baltimore)
A0143	Catholic University of America		Washington
A0018	Children's Hospital, Research Foundation of		Washington
A3026	Ebon Research Systems (NIOSH Lab, West Virginia only)...		Washington
A0434	George Washington University		Washington
A0434	Medical Center		
A0017	Georgetown University Schools of Medicine & Dentistry...		Washington
A2004	Gorgas Memorial Inst of Tropical/Preventive Med Inc		(Washington)
A2004	Gorgas Memorial Laboratory		Panama City and
A2004			Ancon, Panama
A1382	Howard University		Washington
A1382	College of Medicine		
A3033	Nat'l Fish Meal & Oil Assn (via Internat'l Research and		
A3033	Development Corp.: See Michigan)		Washington
A1194	Smithsonian Institution		(Washington)
A1194	Conservation and Research Center		Front Royal, VA
A2066	U.S. Army Institute of Dental Research		Washington
A0019	Veterans Administration Hospital		Washington
A1753	Washington Hospital Center, Research Foundation of		Washington

INSTITUTIONS WITH AN APPROVED ANIMAL CARE ASSURANCE AS OF JANUARY 1983

ASSURANCE NUMBER	STATE/INSTITUTION	ASSURANCE STATUS	CITY
	FLORIDA		
A1899	Bethune-Cookman College		Daytona Beach
A1705	Florida Agricultural and Mechanical University		Tallahassee
A0507	Florida Atlantic University		Boca Raton
A2024	Florida Institute of Technology		Melbourne
A0020	Florida State University		Tallahassee
A1516	Florida, University of		Gainesville
A1516	Health Center		
A0022	Life Sciences Incorporated		St. Petersburg
A2032	Miami Heart Institute		Miami Beach
A0698	Miami, University of		Coral Gables, Miami
A1835	Mount Sinai Medical Center of Greater Miami		Miami Beach
A0698	Papanicolaou Cancer Research Institute at Miami, Inc.		Miami
A1361	South Florida, University of, Medical Center		Tampa
A1516	Veterans Administration Medical Center(Univ. of Florida)		Gainesville
A1755	Veterans Administration Medical Center (James A. Haley).		Tampa
	GEORGIA		
A1707	Albany State College		Albany
A1715	Atlanta University Center		Atlanta
A1715	Atlanta University		
A1715	Clark College		
A1715	Morris College		
A1715	Morehouse School of Medicine		
A1715	Morris Brown College		
A1715	Spelman College		
A1544	Emory University		Atlanta
A1544	Georgia Mental Health Institute		
A1544	Grady Campus		
A1544	Main Campus		
A1544	Yerkes Primate Center		
A1575	Georgia Institute of Technology		Atlanta
A1544	Georgia Mental Health Institute (Emory University)		Atlanta
A0023	Georgia State University		Atlanta
A0697	Georgia, University of and Univ of Georgia Research Fdn.		Athens
A1520	Medical College of Georgia and Medical College of Georgia		
A1520	Research Institute		Augusta
A3039	Mercer University School of Medicine		Macon
A3045	Veterans Administration Medical Center		Augusta
A1544	Yerkes Primate Center (Emory University)		Lawrenceville

INSTITUTIONS WITH AN APPROVED ANIMAL CARE ASSURANCE AS OF JANUARY 1983

ASSURANCE NUMBER	STATE/INSTITUTION	ASSURANCE STATUS	CITY
	HAWAII		
A1574	Hawaii, University of, at Manoa		Honolulu
	IDAHO		
A1873	Idaho State University		Pocatello
A1383	Idaho, University of		Moscow
	ILLINOIS		
A1867	Argonne National Laboratory (U.S. Dept of Energy)		Argonne
A0696	Bradley University		Peoria
A0352	Chicago College of Osteopathic Medicine		Chicago
A1043	Chicago Medical School/University of Hlth Sciences		North Chicago
A1724	Chicago State University		Chicago
A1319	Chicago, University of		Chicago
A1813	Children's Memorial Hospital		Chicago
A0024	Cook Cnty Hospital (Hektoen Inst. f/Med. Res. only)		Chicago
A1371	DePaul University		Chicago
A1730	Evanston Hospital		Evanston
A1878	Harlan E. Moore Heart Research Foundation		Champaign
A1043	Hlth Sciences, University of/Chicago Medical School		North Chicago
A0024	Hektoen Inst for Med. Res. (Cook County Hospital)		Chicago
A1147	IIT Research Institute		Chicago
A1254	Illinois Institute for Developmental Disabilities		Chicago
A2049	Illinois Institute of Technology		Chicago
A1362	Illinois State Psychiatric Institute		Chicago
A1337	Illinois, University of, at Chicago Circle		Chicago
A1084	Illinois, University of, at the Medical Center		Chicago
A1475	Illinois, University of, at Urbana-Champaign		Urbana
A3032	Illinois, University of, Rockford School of Medicine		Rockford
A3014	Loyola University of Chicago, Lake Shore Campus		Chicago
A1540	Loyola University Stritch School of Medicine		Maywood
A0385	Michael Reese Hospital and Medical Center		Chicago
A1879	Mount Sinai Hospital Medical Center of Chicago		Chicago
A1859	Northeastern Illinois University		Chicago
A1042	Northwestern University, Evanston Campus		Evanston
A1042	Chicago Campus		Chicago

INSTITUTIONS WITH AN APPROVED ANIMAL CARE ASSURANCE AS OF JANUARY 1983

ASSURANCE NUMBER	STATE/INSTITUTION	ASSURANCE STATUS	CITY
A1596	Rush-Presbyterian-St. Luke's Medical Center.............		Chicago
A0027	Southern Illinois University at Carbondale..............		Carbondale
A1331	Southern Illinois University at Edwardsville............		Edwardsville
A1774A	Southern Illinois University School of Medicine.........		Springfield
A3002	Veterans Administration Hospital (Edward Hines, Jr.)....		Hines
A1443	Western Illinois University.............................		Macomb
	INDIANA		
A2088	Ball State University...................................		Muncie
A1742	Dow Chemical Co. Res. Ctr.,Hlth/Consumer Products.......		Indianapolis
A1034	Fort Wayne State Hospital and Training Center...........		Fort Wayne
A2063	Harlan Sprague Dawley, Inc..............................		Indianapolis
A1773	Indiana State University................................		Terre Haute
A1407	Indiana University......................................		(Bloomington)
A1407	Campuses: Bloomington, Evansville, Gary, Indianapolis		
A1407	Kokomo, New Albany, South Bend, Terre Haute		
A1407	School of Dentistry (Indianapolis)		
A1622	Laboratory Supply Co., Inc..............................		Indianapolis
A1728	Notre Dame, University of...............................		Notre Dame
A0349	Purdue University-Purdue Research Foundation............		West Lafayette
A0349	School of Pharmacy		
A0349	School of Veterinary Medicine		
A0563	Valparaiso University...................................		Valparaiso
	IOWA		
A3011	College of Osteopathic Medicine and Surgery.............		Des Moines
A0028	Iowa State University of Science and Technology.........		Ames
A1365	Iowa, University of.....................................		Iowa City
A2079	Northern Iowa, University of............................		Cedar Falls
	KANSAS		
A1164	Kansas State University.................................		Manhattan
A0694	Kansas, University of, at Lawrence......................		Lawrence
A0029	Medical Center...................		Kansas City
A1041	Parsons Research Ctr, Bur. of Child Res., U. of Kansas		Parsons
A1311	Washburn University of Topeka...........................		Topeka

INSTITUTIONS WITH AN APPROVED ANIMAL CARE ASSURANCE AS OF JANUARY 1983

ASSURANCE NUMBER	STATE/INSTITUTION	ASSURANCE STATUS	CITY
	KENTUCKY		
A2001	Eastern Kentucky University		Richmond
A1792	Kentucky State University		Frankfort
A1414	Kentucky, University of		Lexington
A1414	Medical Center		
A2096	Louisville, University of, Belknap Campus		Louisville
A0380	School of Medicine		
A2082	Murray State University		Murray
	LOUISIANA		
A0030	Alton Ochsner Medical Foundation		New Orleans
A1874	Delta Regional Primate Research Center (Tulane Univ)		Covington
A2067	Dillard University		New Orleans
A1708	Grambling State University		Grambling
A0471	Gulf South Res. Institute (New Iberia Laboratories)		Baton Rouge
A1368	Louisiana State Univ & Agricultural & Mechanical Coll		Baton Rouge
A1023	Louisiana State University, at Eunice		Eunice
A0031	Medical Center		New Orleans
A0512	Medical Center		Shreveport
A0513	Louisiana Tech University		Ruston
A1369	New Orleans, University of		New Orleans
A1854	Northeast Louisiana University		Monroe
A1874	Tulane University, Delta Regional Primate Res. Ctr		Covington
A1085	School of Medicine		New Orleans
A1354	U.S. Public Health Service Hospital		Carville
A1880	U.S. Public Health Service Hospital		New Orleans
	MAINE		
A0467	Bowdoin College		Brunswick
A2089	Colby College		Waterville
A0032	Jackson Laboratory		Bar Harbor
A0344	Maine Medical Center		Portland
A1568	Maine, University of, at Orono		Orono
A1876	Mount Desert Island Biological Laboratory		Salsbury Cove
A2080	New England, University of, College o/Osteopathic Med		Biddeford
A1894	Southern Maine, University of		Portland

INSTITUTIONS WITH AN APPROVED ANIMAL CARE ASSURANCE AS OF JANUARY 1983

ASSURANCE NUMBER	STATE/INSTITUTION	ASSURANCE STATUS	CITY
	MARYLAND		
A2078	American Foundation for Biological Research............		Rockville
A1334	American National Red Cross Blood Research Laboratory...		Bethesda
A1582	American Type Culture Collection.......................		Rockville
A0033	Baltimore City Hospital (Johns Hopkins University)......		Baltimore
A3630	Biocon, Inc..		Rockville
A3047	Bioqual, Inc...		Rockville
A1839	Biotech Research Laboratories, Inc.....................		Rockville
A2022	Borriston Research Laboratories, Inc...................		Rockville
A1195	Carnegie Institution of Washington, Dept. of Embryology..		Baltimore
A0981	Essex Community College................................		Baltimore County
A1701	Frederick Cancer Research Center (Litton Bionetics, Inc)		Frederick
A3040	Genex Corporation......................................		Rockville
A0033	Good Samaritan Hospital (Johns Hopkins University)......		Baltimore
A2042	John F. Kennedy Institute for Handicapped Children (via		
A2042	Johns Hopkins Univ. for grants NS 13559, 13569 and		
A2042	contracts NSF BNS 7923071 and 8022444-01)..........		Baltimore
A0033	Johns Hopkins University Faculty of Arts and Sciences...		Baltimore
A0033	Schools: Hygiene and Public Health; Medicine.......		
A1701	Litton Bionetics, Inc..................................		Kensington
A1701			Rockville
A1701	Frederick Cancer Research Center...		Frederick
A2063	M.A. Laboratory Animals (Harlan Sprague Dawley Inc.)....		Walkersville
A1751	Maryland, University of, Baltimore County..............		Catonsville
A1729	College Park...................		College Park
A1779	Eastern Shore..................		Princess Anne
A0472	School of Medicine............		Baltimore
A0034	Microbiological Associates.............................		Bethesda
A2087	Spring Valley Laboratories, Inc........................		Sykesville
A2020	Uniformed Services Univ of the Hlth Sciences (DoD)......		Bethesda
	MASSACHUSETTS		
A1341	Abcor, Inc...		Wilmington
A3048	Abiomed..		Danvers
A1163	Amherst College..		Amherst
A0639	Arthur D. Little, Inc..................................		Cambridge
A1576	Beth Israel Hospital...................................		Boston
A1872	Bio-Research Institute Inc.............................		Cambridge
A1535	Boston College...		Chestnut Hill
A1607	Boston University Graduate School of Arts & Sciences....		Boston
A1563	Medical Center		

INSTITUTIONS WITH AN APPROVED ANIMAL CARE ASSURANCE AS OF JANUARY 1983

ASSURANCE NUMBER	STATE/INSTITUTION	ASSURANCE STATUS	CITY
A1620	Brandeis University		Waltham
A1744	Brigham and Women's Hospitals		Boston
A1600	Center for Blood Research		Boston
A0693	Charles River Breeding Laboratories, Inc		Wilmington
A0036	Children's Hospital Medical Center		Boston
A0443	EG&G Mason Research Institute		Worcester
A1570	Eunice Kennedy Shriver Ctr f/Mental Retardation, Inc		Waltham
A0039	Eye Research Institute of Retina Foundation		Boston
A1431	Forsyth Dental Center		Boston
A1456	Harvard Medical School, Dental Medicine, Public Health		Boston
A1326	Harvard University, Faculty of Arts & Sciences		Cambridge
A1363	Joslin Diabetes Foundation, Inc		Boston
A0037	Lahey Clinic Foundation		Boston
A2009	Lowell, University of		Lowell
A1726	Mallory Institute of Pathology Foundation		Boston
A1255	Massachusetts College of Pharmacy		Boston
A1561	Massachusetts Eye and Ear Infirmary		Boston
A1559	Massachusetts General Hospital		Boston
A0038	Massachusetts Institute of Technology		Cambridge
A1456	Massachusetts Mental Health Center		Boston
A0400	Massachusetts, University of, at Amherst		Amherst
A1821	Medical Center		Worcester
A1403	McLean Hospital		Belmont
A0435	Medical Research Institute of Worcester, Inc		Worcester
A1016	Memorial Hospital		Worcester
A1851	Mount Holyoke College		South Hadley
A0035	New England Deaconess Hospital		Boston
A2076	New England Institute for Life Sciences		Waltham
A1269	New England Medical Ctr Hosp.(Tufts-New England Med Ctr)		Boston
A1521	Northeastern University		Boston
A1765	Robert B. Brigham Hospital		Boston
A1628	St. Elizabeth's Hospital of Boston		Boston
A1822	St. Vincent Hospital of Worcester		Worcester
A1162	Sidney Farber Cancer Institute		Boston
A2000	SISA, Inc		Cambridge
A1439	Smith College		Northampton
A3012	Toxicol-Sisa, Inc		Cambridge
A1269	Tufts-New England Medical Center		Boston
A1269	New England Medical Center Hospital		
A1269	Tufts University Schools of Med/Dental Medicine		

INSTITUTIONS WITH AN APPROVED ANIMAL CARE ASSURANCE AS OF JANUARY 1983

ASSURANCE NUMBER	STATE/INSTITUTION	ASSURANCE STATUS	CITY
A2051	Tufts University, Medford Campus		Medford
A1611	Tufts University - Boston		Boston
A1611	Schools of Medicine, Dental Med., Veterinary Med		
A0041	Wellesley College		Wellesley
A2052	Wheaton College		Norton
A1847	Williams College		Williamstown
A0042	Worcester Foundation for Experimental Biology		Shrewsbury
	MICHIGAN		
A0044	Children's Hospital of Michigan		Detroit
A1330	Detroit, University of		Detroit
A1843	Foundation for Behavioral Research		Augusta
A0046	Henry Ford Hospital		Detroit
A1389	Hope College		Holland
A1747	International Research and Development Corporation		Mattawan
A0048	Michigan Cancer Foundation		Detroit
A1487	Michigan State University		East Lansing
A1601	Michigan Technological University		Houghton
A0049	Michigan, University of		(Ann Arbor)
A0049	Campuses : Ann Arbor, Dearborn, Flint		
A0303	Northern Michigan University		Marquette
A1384	Oakland University		Rochester
A0405	Sinai Hospital of Detroit		Detroit
A2063	Spartan Research Animals (Harlan Sprague Dawley Inc)		Haslett
A1895	Wayne County General Hospital		Westland
A0350	Wayne State University		Detroit
A1364	Western Michigan University		Kalamazoo
	MINNESOTA		
A0348	Mayo Foundation		Rochester
A2047	Medical Education & Research Fdn, St. Paul-Ramsey Hosp..		St. Paul
A1509	Minneapolis Medical Research Fdn, Inc		Minneapolis
A1530	Minnesota, University of		Minneapolis
A3010	Saint John's University		Collegeville
	MISSISSIPPI		
A1737	Alcorn State University		Lorman
A1223	Jackson State University		Jackson

INSTITUTIONS WITH AN APPROVED ANIMAL CARE ASSURANCE AS OF JANUARY 1983

ASSURANCE NUMBER	STATE/INSTITUTION	ASSURANCE STATUS	CITY
A2075	Mississippi Industrial College		Holly Springs
A1039	Mississippi, University of, Graduate School		University
A0051	Medical Center		~~Jackson~~
A1837	Southern Mississippi, University of		Hattiesburg
A1700	Tougaloo College		Tougaloo
A1683	Veterans Administration Center		Jackson
	MISSOURI		
A0474	Barnes Hospital (Washington University)		St. Louis
A1849	Central Missouri State University		Warrensburg
A1566	Inst. of Medical Educ./Res.,including St.Louis City Hosp		St. Louis
A0053	Jewish Hospital of St. Louis		St. Louis
A1615	Kansas City College of Osteopathic Medicine		Kansas City
A1722	Lincoln University		Jefferson City
A1585	Midwest Research Institute		Kansas City
A1478	Missouri, University of		(Columbia)
A1478	Campuses: Columbia, St. Louis		
A1478	Campuses: Kansas City; Columbia - Medical School		
A1478	and Laboratory Animal Center		
A1478	Rolla Campus and Sinclair Research Farm		
A0581	Northeast Missouri State University		Kirksville
A0474	St. Louis Children's Hospital (Washington University)		St. Louis
A1566	St. Louis City Hospital, Inst. of Medical Educ. and Res.		St. Louis
A1436	St. Louis University Medical Center		St. Louis
A1791	Saint Luke's Hosp. Fdn for Medical Education/Research		Kansas City
A1240	Southwest Missouri State University		Springfield
A0474	Washington University		St. Louis
A0474	Central Institute for the Deaf		
A0474	Hospitals: Barnes; St. Louis Children's		
	MONTANA		
A1770	Montana State University		Bozeman
A0357	Montana, University of		Missoula
	NEBRASKA		
A1467	Boys Town Inst. for Communication Disorders in Children		
A1467	(Creighton Univ. School of Medicine)		Omaha
A1467	Creighton University School of Medicine		Omaha

INSTITUTIONS WITH AN APPROVED ANIMAL CARE ASSURANCE AS OF JANUARY 1983

ASSURANCE NUMBER	STATE/INSTITUTION	ASSURANCE STATUS	CITY
A1626	Eppley Institute for Research in Cancer		Omaha
A1797	Nebraska, University of - Lincoln		Lincoln
A1626	Medical Center		Omaha
A1347	Omaha		Omaha
	NEVADA		
A1145	Nevada, University of - Reno		Reno
	NEW HAMPSHIRE		
A1353	Dartmouth Medical School		Hanover
A1353	Mary Hitchcock Memorial Hospital (Dartmouth Med School).		Hanover
A1161	New Hampshire, University of		Durham
	NEW JERSEY		
	College of Medicine and Dentistry of New Jersey		
A1750	Middlesex General Hospital (Rutgers Med School)		Piscataway
A0054	New Jersey Dental School		Newark
A0054	New Jersey Medical School		Newark
A1750	Rutgers Medical School		Piscataway
A1750	School of Osteopathic Medicine (Rutgers Med Sch)		Piscataway
A1230	Edward R. Johnstone Training and Research Center		Bordentown
A3050	Food & Drug Res. Labs.,Inc.(Waverly, NY, Res. Ctr only)		Verona
A0691	Institute for Medical Research		Camden
A3034	N.J. Inst. of Technology (N.J. Med Sch, DE 05053 only)		Newark
A1144	N.J. State Department of Health		Trenton
A0058	Newark Beth Israel Medical Center		Newark
A1685	Princeton University		Princeton
A1583	Rutgers University		(New Brunswick)
A1583	Campuses: Camden, Newark, New Brunswick (including		
A1583	Busch and Livingston at Piscataway)		
A3000	Trenton State College		Trenton
A1853	University Laboratories, Inc		Highland Park
A0853	Upsala College		East Orange
	NEW MEXICO		
A0852	Albuquerque, University of		Albuquerque
A2094	College of Santa Fe		Santa Fe

INSTITUTIONS WITH AN APPROVED ANIMAL CARE ASSURANCE AS OF JANUARY 1983

ASSURANCE NUMBER	STATE/INSTITUTION	ASSURANCE STATUS	CITY
A3036	Los Alamos National Laboratory (Univ of California)		Los Alamos
A3051	Lovelace Biomedical/Environmental Research Inst.,Inc. Inhalation Toxicology Research Institute		Albuquerque
A0382	Lovelace Medical Foundation, Research Division		Albuquerque
A1827	New Mexico State University		Las Cruces
A1594	New Mexico Tech (New Mexico Inst of Mining/Technology)		Socorro
A1578	New Mexico, Univnrsity of		Albuquerque
A1578	Schools of Medicine and Pharmacy		
	NEW YORK		
A1754	Adelphi University		Garden City
A0059	Albany Medical College of Union University		Albany
A2073	Animal Medical Center		New York
A2074	Barbara Kopp Geriatric Research Center, Inc		Auburn
A1531	Beth Israel Medical Center		New York
A0060	Bristol Laboratories, Bristol-Myers Co., Res/Dev. Div.		Syracuse
A1455	Bronx Community College (CUNY)		Bronx
A0451	Brookhaven National Laboratory, Associated Universities.		Upton
A1455	Brooklyn College (CUNY)		Brooklyn
A0453	Burke Rehabilitation Center (Cornell Medical College)		White Plains
A1786	Catholic Medical Center of Brooklyn and Queens, Inc		Jamaica
A0061	Children's Hospital of Buffalo		Buffalo
A1455	City College (CUNY)		New York
A0062	Cold Spring Harbor Laboratory		Cold Spring Harbor
A1352	Colgate University		Hamilton
A1271	Columbia University		New York
A1271	Barnard College		
A1271	Health Sciences Division		
A1271	Morningside Campus		
A1320	Cornell University - Ithaca		Ithaca
A1320	College of Veterinary Medicine		
A0453	Cornell University Medical College		New York
A0453	Bourne Laboratories		White Plains
A0453	Burke Rehabilitation Center		White Plains
A0453	New York Hospital		New York
A0641	Eastman Dental Center		Rochester
A0406	Erie County Medical Center		Buffalo
A3050	Food & Drug Res.Ctr of F&D Res.Labs., Verona, NJ		Waverly
A1784	Fordham University		Bronx
A0063	Hospital for Special Surgery		New York
A1455	Hunter College (CUNY)		New York

INSTITUTIONS WITH AN APPROVED ANIMAL CARE ASSURANCE AS OF JANUARY 1983

ASSURANCE NUMBER	STATE/INSTITUTION	ASSURANCE STATUS	CITY
A1455	John Jay College (CUNY)		New York
A1455	Kingsborough Community College (CUNY)		Brooklyn
A1455	LaGuardia Community College (CUNY)		Long Island City
A1455	Lehman College (CUNY)		Bronx
A1803	Lenox Hill Hospital		New York
A1351	Long Island Jewish-Hillside Medical Center		New Hyde Park
A1603	Long Island University		Greenvale
A1603	Campuses: Brooklyn Ctr;C.W.Post Ctr;Southampton Ctr		
A1771	Mary Imogene Bassett Hospital		Cooperstown
A0642	Masonic Medical Research Laboratory		Utica
A1455	Medgar Evers College (CUNY)		Brooklyn
A0930	Medical Foundation of Buffalo, Inc, Research Labs		Buffalo
A0630	Montefiore Hospital and Medical Center		Bronx
A1385	Nassau County Medical Center		East Meadow
A1828	New York Blood Center		New York
A0354	New York, City of, Public Health Research Institute		New York
A0354	incl NYC Dept of Health Bureau of Laboratories		Otisville
A1455	New York, City University of, Res Fdn (CUNY)		
A1455	Listed individually		
A0453	New York Hospital-Cornell Medical Center (Cornell Univ		
A0453	Medical College)		New York
A0959	New York, State of, Dept of Health, Ctr for Labs & Res..		Albany
A0066	Dept of Mental Hygiene, Div of Res		Albany
A1795	Div of Substance Abuse Services,		
A1795	Bur of Labs and Testing		Brooklyn
	State University of New York System-Listed by city		
A1437	State University of New York at Albany		Albany
A0070	State University of New York at Binghamton		Binghamton
A1588	State University of New York College at Brockport		Brockport
A0071	State University of New York Downstate Medical Ctr.		Brooklyn
A0406	State University of New York at Buffalo		Buffalo
A0372	State University of New York, College at Cortland		Cortland
A1315	State University of New York, College at New Paltz.		New Paltz
A0689	State University of New York, Coll. of Optometry		New York
A1420	State University of New York at Oswego		Oswego
A1174	State University of New York College at Plattsburgh		Plattsburgh
A1780	State University College of Arts and Science		Potsdam
A2037	State University of New York College at Purchase		Purchase
A1409	State University of New York at Stony Brook		Stony Brook
A0260A	State University of New York College o/Environmental		
A0260A	Science and Forestry		Syracuse
A0072	State University of New York Upstate Medical Center		Syracuse

INSTITUTIONS WITH AN APPROVED ANIMAL CARE ASSURANCE AS OF JANUARY 1983

ASSURANCE NUMBER	STATE/INSTITUTION	ASSURANCE STATUS	CITY
A1528	New York University Washington Square		New York
A1486	School of Medicine		
A1625	North Shore University Hospital		Manhasset
A1845B	Pace University, Haskins Laboratories of		New York
A1455	Queens College (CUNY)		Flushing
A1455	Queensborough Community College (CUNY)		New York
A1757	Rensselaer Polytechnic Institute		Troy
A1757	Biomedical Engineering Laboratory		
A1562	Rochester, University of, College of Arts and Sciences		Rochester
A1562	Schools of Medicine and Dentistry		
A0067	Rockefeller University Manhattan Campus		New York
A0690	Roswell Park Memorial Institute		Buffalo
A2057	St. John's University		Jamaica
A0068	St. Luke's-Roosevelt Institute for Health Sciences		New York
A1038	St. Mary's Hospital		Rochester
A0069	Sloan-Kettering Institute		New York
A0073	Trudeau Institute, Inc		Saranac Lake
A2060	Union College		Schenectady
A0059	Union University, Albany Medical College of		Albany
A1761	U.S. Public Health Service Hospital		Staten Island
A1631	Vassar College		Poughkeepsie
A3052	Veterans Administration Medical Center		Brooklyn
A2017	Veterans Administration Medical Center		Buffalo
A2068	Veterans Administration Medical Center		New York
A1785	W. Alton Jones Cell Science Center, Inc		Lake Placid
A0464	Yeshiva University, Albert Einstein College of Medicine		Bronx
A1455	York College (CUNY)		Jamaica
	NORTH CAROLINA		
A1418	Duke University		Durham
A2081	East Carolina University		Greenville
A2014	Johnson C. Smith University		Charlotte
A1877	North Carolina Central University		Durham
A0076	North Carolina Fdn for Mental Health Research, Inc		Raleigh
A0650	North Carolina State University		Raleigh
A1459	North Carolina, University of		(Chapel Hill)
A1435	Campuses: Charlotte		
A1459	Chapel Hill - Schools of Medicine and		
A1459	Dentistry		
A1836	Wilmington		

INSTITUTIONS WITH AN APPROVED ANIMAL CARE ASSURANCE AS OF JANUARY 1983

ASSURANCE NUMBER	STATE/INSTITUTION	ASSURANCE STATUS	CITY
A0077	Research Triangle Institute		Res. Triangle Park
A2050	Wake Forest University		Winston-Salem
A0075	Bowman Gray School of Medicine		
A1158	Western Carolina University		Cullowhee
	NORTH DAKOTA		
A1577	North Dakota, University of		Grand Forks
	OHIO		
A1321	Akron, University of		Akron
A1613	Battelle, Columbus Laboratories		Columbus
A1584	Bowling Green State University		Bowling Green
A0407	Case Western Reserve University		Cleveland
A0078	Children's Hospital Medical Center		Cincinnati
A2069	Children's Hospital Research Foundation, Inc		Columbus
A2041	Christ Hospital Institute of Medical Research		Cincinnati
A0079	Cincinnati, University of, Medical Center		Cincinnati
A1479	Cleveland Clinic Foundation		Cleveland
A3021	Cleveland Research Institute		Cleveland
A1604	Cleveland State University		Cleveland
A1410	Dayton, University of		Dayton
A0643	Denison University		Granville
A1293	Kent State University		Kent
A1232	May Institute f/Medical Research of the Jewish Hospital.		Cincinnati
A1569	Medical College of Ohio		Toledo
A0836	Miami University		Oxford
A0465	Mt. Sinai Hospital of Cleveland		Cleveland
A2030	Northeastern Ohio Universities College of Medicine		Rootstown
A0080	Ohio Agricultural Research and Development Center		Wooster
A1462	Ohio State Department of Health		Columbus
A1157	Ohio State University		Columbus
A1157	Colleges; Medicine; Pharmacy		
A1807	Ohio University		Athens
A1327	Ohio Wesleyan University		Delaware
A1809	Saint Luke's Hospital		Cleveland
A1763	Saint Vincent Charity Hospital		Cleveland
A2095	Toledo, University of		Toledo
A1686	Wright State University, including also		Dayton
A1686	Cox Heart Institute (School of Medicine)		
A1686	Fels Research Institute (School of Medicine)		

INSTITUTIONS WITH AN APPROVED ANIMAL CARE ASSURANCE AS OF JANUARY 1983

ASSURANCE NUMBER	STATE/INSTITUTION	ASSURANCE STATUS	CITY
	OKLAHOMA		
A2081	Oklahoma College of Osteopathic Medicine and Surgery		Tulsa
A1272	Oklahoma State University		Stillwater
A0718	Oklahoma, University of		Norman
A1721	Oklahoma, University of, Health Sciences Center		Oklahoma City
A2055	Oral Roberts University		Tulsa
A1169	Southeastern Oklahoma State University		Durant
	OREGON		
A0345	Good Samaritan Hospital and Medical Center		Portland
A0688	Oregon Health Sciences Univ. School of Dentistry		Portland
A0082	Oregon Health Sciences Univ., School of Medicine		Portland
A0360	Oregon Regional Primate Research Center		Beaverton
A1432	Oregon State University		Corvallis
A0438	Oregon, University of, Coll. of Arts and Sciences		Eugene
A1273	Pacific University, College of Optometry		Forest Grove
	PENNSYLVANIA		
A0083	Albert Einstein Medical Center, Northern Division		Philadelphia
A0468	Allegheny-Singer Research Corporation		Pittsburgh
A2019	Beaver College		Glenside
A3041	Biological Corporation of America		West Chester
A3043	Bloomsburg State College		Bloomsburg
A1322	Bryn Mawr College		Bryn Mawr
A1375	California State College		California
A0084	Children's Hospital of Philadelphia (J.Stokes Res. Inst)		Philadelphia
A0390	Children's Hospital of Pittsburgh		Pittsburgh
A1338	Drexel University		Philadelphia
A1474	Eastern Pennsylvania Psychiatric Inst (Med Coll of Pa)		Philadelphia
A1720	Federated Medical Resources		Honey Brook
A0957	Franklin and Marshall College		Lancaster
A3028	Franklin Research Center of Franklin Institute		Philadelphia
A2062	Graduate Hospital		Philadelphia
A1624	Hahnemann Medical College & Hospital		Philadelphia
A1739	Haverford College		Haverford
A0373	Institute for Cancer Research		Philadelphia

INSTITUTIONS WITH AN APPROVED ANIMAL CARE ASSURANCE AS OF JANUARY 1983

ASSURANCE NUMBER	STATE/INSTITUTION	ASSURANCE STATUS	CITY
A0391	Jefferson Medical College of Thomas Jefferson University		Philadelphia
A0084	Joseph Stokes, Jr Research Inst (Children's Hosp, Phila)		Philadelphia
A3024	Lafayette College		Easton
A1399	Lankenau Hospital		Philadelphia
A1558	Lehigh University		Bethlehem
A1711	Lincoln University		Lincoln University
A0437	Magee-Womans Hospital		Pittsburgh
A1323	Medical College of Pennsylvania		Philadelphia
A0057	Merck Sharp & Dohme Research Laboratories		West Point
A1768	Mercy Catholic Medical Ctr of Southeastern Pennsylvania.		Philadelphia
A0085	Milton S. Hershey Med Ctr Coll of Med (Penn State Univ)		Hershey
A2071	Monell Chemical Senses Center		Philadelphia
A0381	Montefiore Hospital		Pittsburgh
A0713	Pennsylvania College of Optometry		Philadelphia
A2044	Pennsylvania College of Podiatric Medicine		Philadelphia
A0956	Pennsylvania Hospital		Philadelphia
A1350	Pennsylvania State University		University Park
A0085	Milton S. Hershey Medical Ctr College of Medicine..		Hershey
A0361	Pennsylvania, University of		Philadelphia
A1037	Philadelphia College of Pharmacy and Science		Philadelphia
A1419	Pittsburgh, University of		Pittsburgh
A0532	Presbyterian-University of Pennsylvania Medical Center..		Philadelphia
A1397	St. Christopher's Hospital for Children (for AM 26606		
A1397	only, via Temple University)		Philadelphia
A1397	Temple University		Philadelphia
A0651	Veterans Administration Hospital (University Drive C)...		Pittsburgh
A0606	Villanova University		Villanova
A1438	Wills Eye Hospital		Philadelphia
A1083	Wistar Institute		Philadelphia
	PUERTO RICO		
A0341	Inter American University of Puerto Rico (for RR 08159		
A0341	only, via Univ of Puerto Rico Medical Campus).....		San Juan
A1740	Puerto Rico, Universidad Catolica de		Ponce
A0415	Puerto Rico, University of		Rio Piedras
A0415	Medical Sciences Campus		San Juan
A2084	Veterans Administration Medical and Regional Office Ctr.		San Juan

INSTITUTIONS WITH AN APPROVED ANIMAL CARE ASSURANCE AS OF JANUARY 1983

ASSURANCE NUMBER	STATE/INSTITUTION	ASSURANCE STATUS	CITY
	RHODE ISLAND		
A1488	Brown University		Providence
A1790	Memorial Hospital		Pawtucket
A1850	Miriam Hospital		Providence
A2029	Rhode Island College		Providence
A0351	Rhode Island Hospital		Providence
A1511	Rhode Island, University of		Kingston
A1745	Roger Williams General Hospital		Providence
	SOUTH CAROLINA		
A1788	Benedict College		Columbia
A3028	E.I.Dupont de Nemours Co,Savannah River Lab,Envr.Tr.Div		Aiken
A0967	Furman University		Greenville
A0388	Medical University of South Carolina		Charleston
A3028	Savannah River Laboratory, Environmental Transport Div.,		
A3028	(E. I. Dupont de Nemours & Co)		Aiken
A1627	South Carolina, University of		Columbia
A3049	Veterans Admin. Med Ctr,Wm. Jennings Bryan Dorn Vet.Hosp		Columbia
A3020	Voorhees College		Denmark
	SOUTH DAKOTA		
A0462	South Dakota, University of		Vermillion
A2053	Yankton College		Yankton
	TENNESSEE		
A1233	East Tennessee State University		Johnson City
A1517	Fisk University		Nashville
A0633	George Peabody College for Teachers (Vanderbilt Univ)		Nashville
A1214	Lemoyne-Owen College		Memphis
A1695	Meharry Medical College		Nashville
A0646	Memphis State University		Memphis
A0633	Middle Tennessee State University (for MH 34277 only,		
A0633	through 2/28/83, via Vanderbilt University)		Murfreesboro
A1035	Oak Ridge Associated Universities, Medical/Hlth Sci Div.		Oak Ridge
A0687	Oak Ridge National Laboratory (Union Carbide Corp)		Oak Ridge
A3037	Oak Ridge Research Institute		Oak Ridge
A0087	St. Jude Children's Research Hospital		Memphis
A0633	Tennessee Neuropsychiatric Institute (Vanderbilt Univ)		Murfreesboro
A1875	Tennessee State University		Nashville

INSTITUTIONS WITH AN APPROVED ANIMAL CARE ASSURANCE AS OF JANUARY 1983

ASSURANCE NUMBER	STATE/INSTITUTION	ASSURANCE STATUS	CITY
A2086	Tennessee Technological University......................		Cookeville
A1286	Tennessee, University of, at Chattanooga................		Chattanooga
A1386	Knoxville, Coll o/Liberal Arts		Knoxville
A1386	Inst o/Agriculture.		Knoxville
A0631	Memorial Research Center......		Knoxville
A0401	Center for the Health Sciences		Memphis
A0633	Vanderbilt University..................................		Nashville
A0633	George Peabody College for Teachers		Nashville
A0633	Tennessee Neuropsychiatric Institute		Murfreesboro
	TEXAS		
A2012	Audie L. Murphy Memorial Veterans Administration Hosp...		San Antonio
A0444	Baylor College of Dentistry............................		Dallas
A1396	Baylor College of Medicine.............................		Houston
A2058	Bishop College (for GM 26992 only, via Univ of Texas		
A2058	Health Science Center at Dallas)..................		Dallas
A0445	Houston, University of.................................		Houston
A1211	Incarnate Word College.................................		San Antonio
A0091	M. D. Anderson Hospital and Tumor Institute (U of Texas		
A0091	System Cancer Center)............................		Houston
A1335	North Texas State University...........................		Denton
A1793	Pan American University................................		Edinburg
A1865	Prairie View A&M University............................		Prairie View
A0362	Rice University..		Houston
A2023	San Antonio State Chest Hospital.......................		San Antonio
A1602	Scott and White Memorial Hospital......................		Temple
A1883	Southern Methodist University..........................		Dallas
A0089	Southwest Foundation for Research and Education.........		San Antonio
A0090	Southwest Research Institute...........................		San Antonio
A2083	Stehlin Foundation for Cancer Research.................		Houston
A1872	Texas A&I University...................................		Kingsville
A1140	Texas A&M University...................................		College Station
A2091	Texas College of Osteopathic Medicine..................		Fort Worth
A1155	Texas Department of Hlth, Bureau of Laboratories........		Austin
A0653	Texas Research Institute of Mental Sciences............		Houston
A1567	Texas Tech University..................................		Lubbock
A1567	Health Sciences Center...........................		Lubbock
A0446	Texas, University of, at Arlington.....................		Arlington
A1496	at Austin........................		Austin
A2010	at Dallas........................		Richardson
A1390	Health Science Center.........		Dallas

INSTITUTIONS WITH AN APPROVED ANIMAL CARE ASSURANCE AS OF JANUARY 1983

ASSURANCE NUMBER	STATE/INSTITUTION	ASSURANCE STATUS	CITY
A1710	at El Paso........................		El Paso
A0652	Medical Branch....................		Galveston
A0355	Health Science Ctr, Dental Branch.		Houston
A1623	Medical School		Houston
A2097	at San Antonio....................		San Antonio
A1687	Health Science Center........		San Antonio
A3035	at Tyler, Health Center...........		Tyler
A1367	Texas Woman's University................................		Denton
A0409	Veterans Administration Medical Center..................		Houston
A2012	Veterans Administration Audie L. Murphy Memorial		
A2012	Veterans' Hospital................................		San Antonio
A1764	Wadley Institutes of Molecular Medicine.................		Dallas
	UTAH		
A0093	Brigham Young University................................		Provo
A1572	LDS Hospital - Deseret Foundation.......................		Salt Lake City
A1029	Utah, University of.....................................		Salt Lake City
A1029	Medical Center		
A2093	Utah, University of, Research Institute.................		Salt Lake City
	VERMONT		
A0410	Institute for Medical Research of Bennington............		Bennington
A1406	Vermont, University of..................................		Burlington
A1406	Medical College		
A1794	Veterans Administration Medical and Regional Office Ctr.		White River Junction
	VIRGINIA		
A2070	Arlington Hospital......................................		Arlington
A1766	Eastern Virginia Medical School.........................		Norfolk
A1581	Flow Laboratories, Inc..................................		McLean
A1556	Hazleton Laboratories America, Inc......................		Vienna
A0094	Medical College of Virginia, of Virginia Commonwlth Univ		Richmond
A0095	Meloy Laboratories, Inc.................................		Springfield
A1735A	Norfolk State University................................		Norfolk
A1299	Old Dominion University.................................		Norfolk
A2021	Richmond, University of.................................		Richmond
A0094	Virginia Commonwealth Univ., Medical College of Virginia		Richmond

INSTITUTIONS WITH AN APPROVED ANIMAL CARE ASSURANCE AS OF JANUARY 1983

ASSURANCE NUMBER	STATE/INSTITUTION	ASSURANCE STATUS	CITY
A1325	Virginia Polytechnic Institute and State University		Blacksburg
A1734	Virginia State University		Petersburg
A1413	Virginia, University of		Charlottesville
	WASHINGTON		
A0466	Battelle Pacific Northwest Laboratories		Richland
A3042	Children's Orthopedic Hospital and Medical Center		Seattle
A1154	Eastern Washington University		Cheney
A3026	Ebon Research Systems (NIOSH Lab., West Virginia only		Rockville
A1731	Fred Hutchinson Cancer Research Center		Seattle
A3046	Genetic Systems Corporation		Seattle
A3016	Institute of Applied Physiology and Medicine		Seattle
A2098	Issaquah Health Research Institute		Issaquah
A1153	Pacific Northwest Research Foundation		Seattle
A1391	Providence Medical Ctr, Reconstructive Cardiovascular		
A1391	Research Center International		Seattle
A0490	Puget Sound Blood Center and Program		Seattle
A1858	Virginia Mason Research Center		Seattle
A0473	Washington State University		Pullman
A0473	Colleges:Education; Pharmacy		
A0481	Washington, University of		Seattle
	WEST VIRGINIA		
A2092	Marshall University		Huntington
A1772	Veterans Administration Medical Center		Martinsburg
A0096	West Virginia University		Morgantown
A0096	Health Sciences facilities; (Dental, Medical,		
A0096	Nursing, Pharmacy Schools)		
	WISCONSIN		
A0655	Blood Center of Southeastern Wisconsin (for HL 26738		
A0655	only, via Mount Sinai Medical Center)		Milwaukee
A2063	Harlan Sprague Dawley Inc		Madison
A1846A	Lawrence University		Appleton
A1457	Madison General Hospital (Univ of Wisconsin, Madison)		Madison
A0365	Marquette University		Milwaukee
A0365A	Medical College of Wisconsin		Milwaukee
A2002	Mount Sinai Medical Center		Milwaukee

INSTITUTIONS WITH AN APPROVED ANIMAL CARE ASSURANCE AS OF JANUARY 1983

ASSURANCE NUMBER	STATE/INSTITUTION	ASSURANCE STATUS	CITY
A1457	Wisconsin, University of................................		(Madison)
A1838	Campuses: Eau Claire		
A3006	Green Bay		
A3007	La Crosse		
A1457	Madison		
A1457	Ctr. for Health Sciences		
A1599	Milwaukee		
A0097	Oshkosh		
A3008	Parkside at Kenosha		
A3009	Stevens Point		
A1698	Superior		
A0963	Whitewater		
	WYOMING		
A1433	Casper College..		Casper
A1434	Wyoming, University of..................................		Laramie

Senator DOLE. Well, again, Senator Melcher has indicated S. 657 may not be the best answer—we think it is in the right direction. We understand there is some opposition; we have tried to accommodate the concerns some have had. We will be working both with APHIS and NIH to resolve this, and it would be very helpful, Dr. Raub if you could give a report on the bill directly to the committee.

Dr. RAUB. We would be pleased to do so.

Senator DOLE. Thank you very much. Our next witness is Stuart Proctor, assistant director, National Affairs Division, American Farm Bureau Federation.

I have your statement which will be made a part of the record. If you can summarize it in 5 minutes, it will be appreciated.[1]

STATEMENT OF STUART PROCTOR, ASSISTANT DIRECTOR, NATIONAL AFFAIRS DIVISION, AMERICAN FARM BUREAU FEDERATION

Mr. PROCTOR. I can summarize it in less than 5 minutes, Senator.

We appreciate the opportunity to be here this morning and present our concern about the humane treatment of laboratory animals.

Farmers have the enviable reputation of being compassionate producers of livestock. And, despite that, we are currently under attack by a number of individuals and associations who make false and inaccurate and misleading statements about things that are done on the farm. These individuals present emotional arguments and exaggerated examples of the way we raise livestock in an attempt to fabricate a problem and to describe one which doesn't actually exist.

We think some of those same emotional arguments are currently made today to describe the laboratory animal problem. We think that Congress is not being presented with sufficient documentation and evidence to describe the problem, and, more importantly, to describe the type of legislation or regulation that is needed.

We think that what has to be kept in mind is that the research that is being conducted today is being done for the benefit of mankind, and we need to be very careful about passing laws or imposing regulations which would impede that research.

In order to provide the Senate with the kinds of information we think is necessary to legislate on this issue, we are supporting bill No. S. 964, introduced, as you know, by Senators Hatch and Kennedy. We think this will provide, again, the type of information that is needed.

The interest in further investigation of the seriousness of this problem seems to be gaining recognition in the Senate. A recently issued report by the Labor and Human Resources Committee says that the extent of the problem is unclear. Another report that was recently issued by the Committee on Appropriations expresses concern about the effectiveness of the enforcement of the Animal Welfare Act, and they go on to recommend that GAO conduct a study of the enforcement of the act.

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[1] See p. 155 for the prepared statement of Mr. Proctor.

We think that this report which recently passed the Senate gives us an indication that perhaps we have an enforcement problem which could be solved by administrative action and perhaps additional funding rather than through legislation.

Since the farm and laboratory animal welfarists appear to be interested in passing legislation for emotional reasons, we are also concerned about future amendments of the Animal Welfare Act which would bring agricultural research under the jurisdiction of the legislation.

And you know, Senator, what the effect that would be on production research, agriculture production research.

So just to quickly summarize, we are concerned about laboratory animals, we are concerned about the type of precedent that is being generated by the issue, by the interest in the legislation. And, finally, we are also interested in research being done for humane reasons and anything to impede that research.

Senator DOLE. Thank you very much. I guess what you are saying, is the study bill introduced by Hatch and Kennedy, may address the same issues as S. 657.

Mr. PROCTOR. Yes, I think what we are trying to say is S. 657 may be appropriate, but before we look at S. 657 in more detail, we would like to have some additional facts. And after looking over S. 657, and particularly the provisions in section 4(b) of that act, it seems to be a very moderate approach to us; it seems to us that we need the kind of information that would be generated by the National Academy of Sciences, or some other organization, before we go about legislating and passing regulations.

Senator DOLE. We certainly appreciate your testimony. The American Farm Bureau is a great organization; we hope we can work out something that will have your support. This bill may not, as Senator Melcher indicated, be a perfect vehicle, but it is something that deserves more attention. There are millions of people interested in this type of legislation who aren't out there trying to do in the American farmer. I am not and I don't think Senator Melcher is.

Mr. PROCTOR. We understand that, Senator, and appreciate your support of agriculture, but we merely try to draw the parallel that some of the same people who are interested in the laboratory animal legislation are also interested in making changes in farm animal legislation which would restrict or set up guidelines or perhaps get the Government involved in the way we raise livestock in this country, and we were just trying merely to show that parallel.

Senator DOLE. Thank you very much. Testifying next, as a panel, are Charles Chambers, executive director, American Institute of Biological Sciences; Dr. Frank Standaert, chairman of the Department of Pharmacology, Georgetown University School of Medicine, accompanied by Dr. John Sherman, vice president of the American Association of Medical Colleges; and Dr. Walter Randall, professor of physiology, Loyola University of Chicago, representing the American Physiological Society.

I would like to insert into the record while they are coming forward a letter and a mailgram from the American Physiological Society—in fact, the mailgram is from Dr. Randall.

We have made the changes suggested in the letter dated February 10, 1983, from Dr. Reynolds, executive vice president of the American Physiological Society, and we appreciate the supportive mailgram from Dr. Randall, of April 10, 1983. I will ask that the letter and the mailgram be made a part of the record.

[The following material was received by the committee:]

THE AMERICAN PHYSIOLOGICAL SOCIETY,
Bethesda, Md., February 10, 1983.

Senator ROBERT J. DOLE,
Hart Senate Office Building,
Washington, D.C.

DEAR SENATOR DOLE: The American Physiological Society appreciates the opportunity to review the draft version of the "Improved Standards for Laboratory Animals Act" and applauds your efforts to develop a legislative proposal that would be meaningful to the interests of both the research community and the humane societies.

The Society's interests in this proposed legislation is paramount because physiologists use more than half of the animals required for biomedical and behavioral research and for teaching. Your efforts to achieve uniform standards for the utilization of laboratory animals by providing amendments to the Animal Welfare Act is a position the Society has advocated for more than one year, should any legislation be deemed necessary.

By and large, the Society could support the proposed amendments to the Animal Welfare Act if language changes were made in several sections. The sections of concern to the Society are:

Page 5, line 4. The Society recommends the insertion of the words "unacceptable to the committee" so that the line would read: ". . . animal care or treatment, or any deviations unacceptable to the committee of research. . . ."

Rationale.—There always will be some deviation of research methodologies within the experimental design of the project and such deviations could be approved by the institutional animal studies committee and, therefore, would not need to be reported as a deviation, thus eliminating needless paperwork for the committee.

Page 5, lines 16-21. It is the Society's recommendation that the following sentence be added to this section: "Such notification shall be made only after the appropriate representative of the parent organization has been notified by the committee of the unacceptable conditions and that the required actions for correction have not been taken."

Rationale.—The parent institution should be permitted the opportunity to make any corrections of unacceptable conditions before such conditions are reported to a Federal agency.

Page 5, lines 31-33. The Society recommends that this paragraph be deleted or that it be included as part of the requirements for the clearinghouse described on page 6, amendment (e).

Rationale.—It is neither feasible nor appropriate for the committee to provide instruction or training in means to prevent unnecessary duplication and repetition of animal experimentation by research facilities. This basically is a judgment decision of scientists and teachers and information should be provided to them by the clearinghouse to assist in such decision making.

Page 6, lines 12-18. The Society recommends that this section be rewritten to eliminate its vagueness and to provide more specific responsibilities of the clearinghouse functions. Also, inasmuch as this legislation amends the Animal Welfare Act, the Society recommends that consideration be given to placing the clearinghouse in the National Agricultural Library rather than the National Library of Medicine.

Rationale.—This potentially is a valuable provision of the bill but as presented, it is too vague to assure useful implementation. It should be made clear that the clearinghouse responsibilities should include information on improved methods for animal experimentation (e.g., anesthetic procedures) and methods and models not involving animal use including means to prevent unnecessary duplication and repetition of animal and experimentation.

Page 6, line 23. The Society recommends that the word "or" be changed to "and" so that it would read: ". . . the Secretary of Agriculture [or] *and* to the Secretary of any . . .".

Rationale.—This assures that proper notification of assurance of compliance is made to all of the agencies involved and not to just one of several possible agencies.

Page 7, lines 2-5. The Society recommends that the language in this section be changed so that lines 3 through 5 would read: ". . . conscious animals, appropriate assurances that [the services of] a doctor of veterinary medicine [have been employed] *had been consulted* in the planning of such procedures;"

Rationale.—The term "employed" has the connotation of extra costs to many institutions that do not have a staff veterinarian, and would believe that one would have to be employed by the institution.

The Society is grateful for having this opportunity to express its views on the proposed "Improved Standards for Laboratory Animals Act" and looks forward to continuing working with your staff on this legislative initiative.

Sincerely yours,

ORR E. REYNOLDS, Ph. D.,
Executive Vice President.

[Western Union Mailgram]

CHICAGO, ILL., *April 10, 1983.*

Senator ROBERT J. DOLE,
U.S. Senate,
Washington, D.C.

If the Congress elects to enact legislation relating to the care and treatment of laboratory animals, the American Physiological Society would encourage the Congress to adopt the proposed "Improved Standards for Laboratory Animals Act" (S657) as the most constructive course of action at this time.

It is the judgment of the Society's counsels that S657 provides a logical approach to ensuring the care and treatment of laboratory animals because it would amend current provisions of the Animal Welfare Act which has established standards for entities involved in bio-medical and behavioral research that includes the use of animals.

A similar legislative proposal, an amendment to the "National Institutes of Health Renewal Authorizations" (HR1555), is limited in its scope to only those NIH funded programs and, therefore, fails to address the entities which use the majority of laboratory animals.

Enactment of S657 would be complementary to the proposed "Animal Welfare in Research Study Act of 1983" (S964) which would provide for 18 months study of all the issues concerning the use of animals in research.

Therefore, if legislation is to be enacted by the Congress the American Physiological Society would support the passage of the "Improved Standards for Laboratory Animals Act" at this time.

WALTER RANDALL, Ph. D., *President.*

Senator DOLE. Again, I will ask the panel to summarize your statements; I do have some questions and we do have a time problem. So if you can summarize your concerns, I would appreciate it. Dr. Randall.

STATEMENT OF DR. WALTER RANDALL, PROFESSOR OF PHYSIOLOGY, LOYOLA UNIVERSITY OF CHICAGO, STRITCH SCHOOL OF MEDICINE, REPRESENTING THE AMERICAN PHYSIOLOGICAL SOCIETY, ACCOMPANIED BY DR. ORR REYNOLDS AND WILLIAM SAMUELS

Dr. RANDALL. Mr. Chairman and members of the group. My name is Walter Randall and with me are Dr. Orr Reynolds and Bill Samuels of the American Physiological Society.

I am the immediate past president of the American Physiological Society which represents some 6,000 physiologists actively engaged in the use of laboratory animals for the purposes of biomedical research and teaching.

Physiology is the study of how living beings function, and, therefore, it is understandable that physiologists are the largest users of live animal models for research. More than half the total number of animals required are used for cardiovascular, neurophysiological, endocrinological, respiratory research.

My work for the last 29 years at Chicago's Stritch School of Medicine—I served there 21 years as chairman of physiology—is in cardiovascular research. Also, I am a living beneficiary of this area of research as last year I underwent quadruple aorta coronary bypass surgery and I have some intimate feeling of the contributions of animal research to that direct medical application.

I am here in the conviction that 80 percent of the diagnosis and treatment I received was not known to medicine 5 or even 15 years ago. The advances in bypass surgery are based entirely on animal-oriented cardiovascular surgery.

The American Physiological Society recognizes that the use of laboratory animals for biomedical research and teaching will continue to be required if we are to advance in knowledge and if we are to continue to train tomorrow's physicians and scientists. We need, of course, to conserve and use our animal resources.

The need for animal models will never be eliminated for the purpose of research and teaching. But it should be noted that the numbers of animal species used for these purposes are declining through the voluntary efforts of scientists and educators. A recent survey by the society has documented precisely that point and the documentation is in that statement that you have already seen.

It is unfortunate that there now is a preconceived notion that restrictive Federal legislation is needed despite verified trends which display marked reductions in the number of animals being used in both research and teaching. There is conclusive evidence from Federal agency records that both the guidelines of the National Institutes of Health and the standards of the Animal Welfare Act are accepted and followed by responsible researchers and scientists using living animal models.

By and large, statements of malicious laboratory animal abuse by those who oppose animal research and scientific inquiry are anecdotal and are largely without verification. Such statements are designed, in my opinion, to sow seeds of mistrust about science and research in the minds of those unfamiliar with the standards and regulations that govern all research practices involving the use of laboratory animals.

It is because of such anecdotal testimony that the society maintains its position that restrictive legislation is not needed. The Congress already has provided the mechanism for the assurances of proper care and treatment of laboratory animals with the enactment and subsequent amendments to the Animal Welfare Act. In addition to this act, the National Institutes of Health has established guidelines for the care of laboratory animals and the American Physiological Society as well as several other national scientific societies have had standards for animal care and treatment which predate all such Federal initiatives. It is a matter of record that the American Physiological Society's guidelines for laboratory animal care were the original basis for both the NIH guidelines and the Animal Welfare Act.

However, if the Congress honestly believes that further restrictive legislation is needed for animal research, then the Society supports the concept of S. 657.

The purpose of S. 657 is to amend the Animal Welfare Act, currently the only legislative authority governing the use of animals.

It is for this reason that the Society opposes proposals that would place similar legislative authorities in other departments of the Federal Government since such action would lead to a divergence of standards and regulations, causing much confusion to researchers and increasing both the institutional and Federal costs in monitoring the Nation's biomedical research programs.

The concept of amending the Animal Welfare Act has the merit of encompassing all facets of animal use in research and testing unlike other proposals which are limited to those awarded grants and contracts from the U.S. Department of Health and Human Services.

Thus, it is the judgment of the American Physiological Society that S. 657 provides a logical approach to ensuring continued standards for the care and treatment of laboratory animals and it is within this framework that the Society would give its qualified support. But it must be noted that there are areas within the currently proposed bill that are of major concern to all physiologists and other scientists who are involved with animal experimentation.

One such major concern is the proposal to involve the Secretary of Agriculture in the promulgation of standards for research facilities, including requirements for methodologies in experimental procedures. Support from the research community for the enactment of the Animal Welfare Act came from the fact that Congress at that time saw fit to prohibit any interference of research protocols by the Secretary. That prohibition is still paramount in importance to the researcher. Without this prohibition continuance in the law, biomedical research will become more restrictive in its scope than any law that could be enacted by Congress. To involve the Secretary of Agriculture in setting standards for research methodologies and procedures would stifle individuals now engaged in research. It also would distract the brightest young minds from careers in biomedical research.

If legislative measures are needed at this time, the American Physiological Society encourages the concept of making amendments to the Animal Welfare Act. However, the society encourages this committee to give serious consideration to the facts concerning the issues cited above before acting on passage of this legislation. A study of the issues and questions involved is vital before putting any new restrictions into place that may soon prove to be undesirable. You risk serious curtailment in the spectacular development of new knowledge which contributes to the control of disease.

Many of the answers to your questions could come from a study proposed by Hatch and Kennedy. It is the society's belief that this study would be complementary to S. 657. The society also believes an objective study would show that restrictive legislation is unnecessary and potentially dangerous.

The society is grateful for this opportunity to express its views, not only of the group but the constituency, and appreciates the efforts of Senator Dole for permitting us to review and comment on this proposal.

It would be my pleasure to respond to the members of the committee who may have questions about the society and its position on S. 657.

Thank you

Senator Dole. You have appended to your statement an informational page entitled "Guiding Principles in the Care and Use of Animals." I note that paragraph 3 indicates "Animals in the laboratory must receive every consideration for their comfort; they must be properly housed, fed, and their surroundings kept in a sanitary condition."

So it appears that you are in total agreement with changing the term "minimum" to "proper" as in our bill, though APHIS may have some problems with it.

That will be made a part of the record.

[The following material was received by the committee:]

Guiding Principles in the Care and Use of Animals

(APPROVED BY THE COUNCIL OF THE AMERICAN PHYSIOLOGICAL SOCIETY)[1]

Animal experiments are to be undertaken only with the purpose of advancing knowledge. Consideration should be given to the appropriateness of experimental procedures, species of animals used, and number of animals required.

Only animals that are lawfuly acquired shall be used in this laboratory, and their retention and use shall be in every case in compliance with federal, state and local laws and regulations, and in accordance with the NIH Guide.[2]

Animals in the laboratory must receive every consideration for their comfort; they must be properly housed, fed, and their surroundings kept in a sanitary condition.

Appropriate anesthetics must be used to eliminate sensibility to pain during all surgical procedures. Where recovery from anesthesia is necessary during the study, acceptable technique to minimize pain must be followed. Muscle relaxants or paralytics are not anesthetics and they should not be used alone for surgical restraint. They may be used for surgery in conjunction with drugs known to produce adequate analgesia. Where use of anesthetics would negate the results of the experiments such procedures should be carried out in strict accordance with the NIH Guide.[2] If the study requires the death of the animal, the animal must be killed in a humane manner at the conclusion of the observations.

The postoperative care of animals should be such as to minimize discomfort and pain, and in any case shall be equivalent to accepted practices in schools of veterinary medicine.

When animals are used by students for their education or the advancement of science, such work shall be under the direct supervision of an experienced teacher or investigator. The rules for the care of such animals must be the same as for animals used for research.

——— ——— *Investigator.*

Senator Dole. Let me hear from the other members of the panel.

STATEMENT OF FRANK STANDAERT, M.D., CHAIRMAN, DEPARTMENT OF PHARMACOLOGY, GEORGETOWN UNIVERSITY, SCHOOL OF MEDICINE, REPRESENTING THE AMERICAN ASSOCIATION OF MEDICAL COLLEGES, ACCOMPANIED BY DR. JOHN SHERMAN, VICE PRESIDENT, AMERICAN ASSOCIATION OF MEDICAL COLLEGES

Dr. Standaert. Senator Dole, I am Dr. Frank Standaert, chairman of the Department of Pharmacology at Georgetown. I am here today with Dr. John Sherman, and we speak on behalf of the American Association of Medical Colleges.

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[1] Revised 1980.

[2] Guide for the Care and Use of Laboratory Animals, NIH Publication No. 80-23, Revised 1978, Reprinted 1980, Office of Science and Health Reports, DRR/NIH, Bethesda, MD 20205.

We welcome the opportunity to testify on your bill, to improve the standards of care for laboratory animals and their use in research.

The association serves as the national voice for 127 accredited medical schools and their students, more than 400 of the major teaching hospitals in the United States, and over 70 academic and professional societies whose members are engaged in medical school teaching, patient care, and research. And, in addition, the National Association of State Universities and Land Grant Colleges has authorized me to indicate their concurrence in the position that we will present.

The AAMC's interest in this bill is clear: advances in patient care are totally dependent upon progress in biomedical research; and in this, historically, the role of the laboratory animal has been central and critical to essentially every breakthrough in research.

Over the last four decades, medical school research capacity has enormously expanded, knowledge in the biological and medical sciences has grown very rapidly and the application of that new knowledge has resulted in profound improvements in the understanding as well as in the prevention, diagnosis, and treatment of human disease. The growth in the research enterprise has been paralleled by increasing attention and sensitivity to the humane use of experimental animals. The AAMC is aware of no evidence that systematic deficiencies exist within academic medical centers in the care, treatment, and use of animals.

With this conviction, we are simultaneously faced with a spate of bills that would substantially escalate animal welfare regulation. Therefore, the association has reacted positively to S. 964, the bill introduced by Senators Hatch and Kennedy and subsequently incorporated into the NIH reauthorization bill. This proposal would require a comprehensive study by the National Academy of Sciences of the current animal welfare activities, assessment of the standards of care in research, a review of existing State and Federal laws governing animal research, a review of the numbers and types of animals used in research, and an assessment of the costs of laboratory animal accreditation.

A slightly different measure, proposed by Representative Madigan, has now been incorporated into the House of Representatives bill H.R. 2350.

Enactment of either of these proposed studies would provide the Congress with specific, authoritative and timely information upon which the need, if any, for future legislation could be predicated. Should such a need be demonstrable, a rational basis will have been established for specifying the appropriate content of corrective legislation. Last April, this association, along with 62 other scientific organizations, advanced this point of view in a letter to each member of the Senate. The AAMC respectfully requests that a copy of this letter be entered into the record, together with a list of scientific organizations that have subsequently subscribed to its contents.[1]

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[1] See p. 161 for the above-referred to letter printed as an attachment to a letter from Claude Migeon, Endocrine Soceity.

Senator Dole. That will be made a part of the record.

Dr. Standaert. Thus, it should be evident that the AAMC's first objection to S. 657, as well as to any other substantive legislation on this subject, is that it is premature. To escalate the amount of Government regulation in the absence of demonstrable systemic problems seems unwise.

The bill under consideration deals with a complex set of issues. In the short time available, those provisions that are of the greatest concern to the association will be noted.

On the positive side, S. 657, by amending the Animal Welfare Act, preserves a single Federal legislative focus for animal welfare regulatory activity under this statute. This avoids the many problems that would inevitably arise if responsibility for this function were scattered through multiple statutes

Despite this desirable feature, other features of this bill would impact adversely on biomedical and behavioral research.

The time honored and proven peer review process for assessment of research proposals is compromised by at least three provisions. First, the Secretary is required to "promulgate standards for research facilities, including proper requirements for animal care, treatment, and methodology in experimental procedures to insure that animal pain and distress are minimized." Assessment of research methodologies in biomedical and behavioral research fall within the province of the NIH peer review system, where applications for support are evaluated by scientific experts in the discipline or field or specialty cognate of specific proposals. It is not reasonable to expect the USDA to be able to promulgate standards covering this vast range of research. But it is even more unreasonable to expect that inspectors from the Department's Animal Health and Plant Inspection Service, who would be required to verify compliance with these standards, would be qualified to reach sound and informed scientific judgments over so wide a spectrum of science. Those inspectors are characteristically doctors of veterinary medicine with little, if any, training in biomedical research.

Second, the restraints now imposed on the authority of the Secretary to not interfere with research—are significantly attenuated. Lifting the existing statutory prohibition from interference with the "conduct of research" strongly implies that the Secretary would, under the terms of the bill, possess the authority to do so. The presumed intent of this modification is to facilitate regulation of research methods and practices. But the latter is properly the responsibility of scientific experts, operating within the peer review system.

Third, animal study committees are assigned responsibility for the review, as part of their inspection of the research facility, of "research methods and practices . . . to insure compliance with the standards of appropriate care, treatment and methodology . . .". Again, an inappropriate agent, the animal study committee, is assigned a responsibility that properly belongs to, and can best be discharged by, expert scientists in a peer review context. No single institution could constitute a committee with the breadth of expertise required.

In addition to compromising the peer review process, there are costs implicit in the bill which would constitute another serious threat to science, since there is conspicuous absence in this proposal of provisions for funding. Without new funds, the very substantial costs of compliance would presumably have to come from funds, private or public, that otherwise would be spent on research. The indirect costs of Federal research awards, whose recent increases have been of deep concern to Congress, would surely rise, again reducing the funds available for research.

We are not certain how upgrading standards from minimum to proper requirements for handling, housing, feeding, watering, sanitation, ventilation and shelter from extremes of weather and temperature would be implemented. The most reasonable assumption, absent language to the contrary, is suggested by your introductory statement that uniform standards based on the NIH guide would be adopted. The AAMC believes that animal facilities in its constituent institutions are adequate and provide acceptable conditions for experimental animals.

Some institutions, however, do not now meet the optimal standards that NIH has set as a target. Should absolute compliance with these targets be demanded and the stretchouts of cost that are now permitted by NIH be eliminated, institutions would be required to make huge fiscal outlays or to terminate some very important research that is ongoing.

Other costly items in the bill include: expanded requirements placed upon the institutional animal study committees, for example, the amplified reporting, notification and educational responsibilities; the duplicative assurance requirements; the information service that the National Agriculture Library would be required to provide; and the implied intensification of the APHIS inspection procedures.

Mr. Chairman, S. 657 is major legislation that would adversely affect the Nation's biomedical and behavioral research enterprise. Its price tag, assuredly high even if precisely unspecifiable, would, absent any funding provisions, be at the expense of ongoing research. Moreover, individuals who rarely, if ever, would possess the qualifications of the scientific experts participating in the nationally managed peer review systems would be authorized to interfere with the ongoing peer-approved research. In spite of this, the evidential basis that current conditions are systematically flawed and that additional regulation is needed is highly fragmentary, anecdotal, and inadequate. With almost 700 institutions engaged in federally supported research, the number of instances in which animal welfare has been compromised is minuscule. Therefore, the AAMC strongly recommends that specific animal welfare legislation be held in abeyance until such time as a comprehensive assessment of the need, together with cost estimates, has been carried out by a responsible body, such as the National Academy of Sciences.

I thank you for the opportunity to allow us to present our position, and I would be happy to answer any questions you might direct to us.

Senator DOLE. Let me include at this point in the record a letter from Mr. Chambers concerning the testimony prepared by Dr. Jordan.

[The following letter was received by the committee:]

AMERICAN INSTITUTE OF BIOLOGICAL SCIENCES,
Arlington, Va., July 19, 1983.

Hon. ROBERT J. DOLE,
U.S. Senate,
Washington, D.C.

DEAR SENATOR DOLE: The American Institute of Biological Sciences appreciates the opportunity to express its views on bill S. 657, introduced by you to amend the Animal Welfare Act to ensure the proper treatment of laboratory animals.

I am pleased to enclose a copy of testimony prepared by Dr. John Patrick Jordan, Chairman of the AIBS Committee on Public Responsibilities, which is charged with studying and reporting on all matters of public interest that pertain to biology. Dr. Jordan's statement incorporates the AIBS Policy Statement regarding the use of animals in experimentation and concludes that the amendment is a logical approach to continuing the standards and procedures already established, and one deserving of AIBS support.

Unfortunately, Dr. Jordan's schedule prevents his attendance at your hearings on July 20. We are grateful for the invitation to appear and I shall be present on Dr. Jordan's behalf. I shall be joined by Donald R. Beem, Assistant Executive Director of the Institute and our senior staff biologist. I shall also recognize the presence of Dr. Orr E. Reynolds, Executive Secretary of the American Physiological Society and a member of the AIBS Executive Committee.

Thank you for your kind attention to our testimony and we look forward to offering additional information to you and your colleagues at the hearings.

Sincerely,

CHARLES M. CHAMBERS,
Executive Director.

Senator DOLE. I have read the testimony. Rather than reading it to me again, why don't you summarize it quickly—we have to leave here at 11, and we still have two other witnesses. If you could summarize it in a couple of minutes I will ask some questions.[1]

STATEMENT OF CHARLES CHAMBERS, EXECUTIVE DIRECTOR, AMERICAN INSTITUTE OF BIOLOGICAL SCIENCES

Mr. CHAMBERS. It would be my pleasure. Just to summarize briefly the points of relationship to the legislation that is under review here, our institute is a federation of some three dozen biological, medical, and agricultural societies, with a longstanding interest in the issues raised in this hearing.

Our major emphasis in the testimony regards the quality of research data, the ethics of handling research animals, and the overall respect for life, especially in the educational setting.

We consider that the use of replicable experiments is an indispensable element of scientific validation, and, in order to assure that the knowledge that is obtained in the laboratory is sound enough to be used for the improvement of human welfare, the validation of that data through replication of the experiments is essential.

At the same time, we do feel that the concept of an animal study committee is one that is well-implemented and well-supported within our membership. There has been some concern about the role of the public representative in those committees. However, it is our feeling that these public representatives play a very important and useful role in helping to maintain the local autonomy and governance of our institutions of higher education.

We have experienced a crisis in general science literacy in this country, and it is our feeling that the work of the animal study committees, with their public representatives, will help broaden the understanding of the important and essential role played by animal specimens in research and education.

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[1] See p. 71 for the prepared statement of Mr. Jordan.

It is also a cornerstone of our policy position, which is of a few years standing, that good research data goes hand in hand with good animal care. It is not possible to conduct sound scientific research with animals that have not been well cared for. Many of our organizations are involved in developing livestock to meet the food and nutrition needs of lesser developed countries, and there is no way that the disease-resistance and environmental-resistance qualities of this livestock can be validated unless the animals are given the highest care in the experimental setting.

The role of making the institution accountable to an animal study committee again is in consonance with the concept of self-regulation in higher education and research, and is to be preferred, as proposed in this legislation, over a new, expanded role for Federal regulators.

At the educational level, it is our firm belief that the study of animals enhances student sensitivity to and understanding of living creatures, and that intrusive studies, especially at the lower collegiate and high school levels, should be avoided, especially where the teachers can rely on demonstration and observation rather than actual experimentation with those animals. If experimentation is needed, then the animals in the lowest phyla consistent with the educational result should be used.

It is our belief that even without added legislation, there will be continued attention to animal welfare needs in our research and teaching institutions, and would feel that if the research and fact-finding, which this committee does, indicate that further legislation is needed, then it is a logical approach to consider amending the current Animal Welfare Act in many of the ways proposed by the legislation, although we would hope that we would have an opportunity to work further on fine tuning those details.

That is the basic thrust of our presentation, Senator, and we would like to thank you for the opportunity to offer these views.

Senator DOLE. As I understand the legislative situation, the so-called study proposed by Senators Hatch and Kennedy is part of the NIH reauthorization. We would like to offer a substitute when the NIH bill comes to the floor. Why can't we hammer out these differences in 2 weeks, rather than waiting 18 months?

Every time this type of legislation is considered someone suggests that we have a study. What can't we do in 2 weeks that we can do in 18 months?

Back in 1967, when animal welfare legislation was pending, everyone called for a study. The National Society for Medical Research asked for an exercise study. We study everything around here; we do a lot of it in the Finance Committee.

With all the people we have here today why can't we work out a legislative proposal which could substitute for the study? It will save all the taxpayers money, probably enough to take care of the problem.

Dr. STANDAERT. This is somewhat different than the earlier studies. We are asking for a study because if there are problems, they should be addressed; but those problems should be identified before blanket legislation.

To me it would be premature to pass legislation before an authority such as the NIH—and it would only be one of the problems that they would deal with—has really dug into and found out what the specific problems are so that the legislation could be targeted to the problem and help those of us who truly want to improve the care of the animals, to help us accomplish that, rather than just pass blanket legislation that we are going to have to face——

Senator DOLE. It's a small blanket, I might say.

Dr. STANDAERT. It might not be to the people in the institutions. Our proposals are already reviewed many, many times, reviewed by the department chairman, reviewed by the NIH or the NSF, or whatever agency it goes to, and those panels which I have been on for many years very carefully look at animals. They are reviewed again when the results are submitted for publication, because almost all of the major journals have adopted the APS's standards and will not publish material unless the author is willing to certify that the research was conducted in that way.

So we have many reviews already. And just another review that is not targeted at uncovering specific problems would be just that much more administrative work for those of us in universities who are already strapped with that kind of thing.

Senator DOLE. Well, if AAMC objects to reviewing what is done to animals during experimentation, how can we assure the public that animals are being treated humanely?

Dr. STANDAERT. We are not objecting to it; we are asking that—in fact, that a survey or study or intensive expert study be done to uncover what, if any, instances of abuse are occurring, and that those be addressed specifically.

Senator DOLE. If you let the public look, you might not need the study. Who is going to study it, the same people who are doing it?

Dr. STANDAERT. We are recommending the Academy of Sciences; we would have no particular objection to any other expert group of people, which could very well, as many academy committees do, include public members.

Dr. SHERMAN. Mr. Chairman, may I comment on that?

Senator DOLE. Sure.

Dr. SHERMAN. There is such a wide divergence of opinion now as to the extent of the problem that in the absence of data and any study of any recent origin, it would seem almost impossible for Congress to determine which of those opinions, those objecting to legislation or those proposing legislation, are on the more solid ground.

And for that reason, the fact that there has not been a definitive study in this area for years, we suggest that, however that study comes out, it would provide the basis for appropriate legislation.

Senator DOLE. Well, does it take 18 months to do that? Is that an arbitrary figure?

Dr. SHERMAN. By the time that the contract process and the other activities associated with the study—it could take—I would suggest that would be a maximum, not a necessary period.

Senator Dole. We had a commission that solved the social security problem in a year. I don't know why it would take 18 months for this.

Dr. Standaert. I think that is purely a logistics problem between the contracting agency and the Government. If the Government said we want this done in 6 months, and we are willing to put the resources in, I am sure it could be done in 6 months; 18 months, as he said, is an outside maximum. We are not trying to stall this indefinitely.

Senator Dole. Well, if we shorten the study up to 6 months, that would be a plus.

Dr. Standaert. As far as we are concerned, we would like a good comprehensive study as fast as it is possible to logistically handle that. It is not a question of indefinite stalling; it is a question of having the facts.

Senator Dole. I am not questioning anyone's motives; I am just trying to see how we can address the problem, because Congress moves rather slowly. We don't study everything before we vote around here, unfortunately. Or maybe fortunately, depending on your point of view.

We are appointing a lot of commissions these days; we are going to abolish Congress one of these days.

Dr. Standaert. One major part of that study is being conducted by NIH right now. It will be done within, Dr. Raub said, presumably within the next few months, an onsite field inspection will be done.

Senator Dole. Based on the statements, everybody appears, so far, to be men of good will. We can hammer out something.

I understand that many of your concerns, Dr. Randall, have been addressed. We have amended the bill a number of places. There are still areas that you think we need to address. Is methodology a concern?

Dr. Randall. Yes, I think that the bill as it stands now is not acceptable yet to us because of the implications of the statement regarding the interfacing of the Secretary of Agriculture—the definition of "methodologies and procedures" is something that requires real expertise. For one to be on the line, doing the experiment, doing the research, he has to be knowledgeable. I could give examples which would describe the precise implications of an experimental protocol which rides or falls depending on the characteristics of the anesthetic, the characteristics of the instrumentation.

And the individual who has only textbook knowledge of this simply isn't qualified to make the judgment. And therefore the peer review, it seems to me, is an attempt to bring the very focus on research. Research is right at the fringe of knowledge, by definition, and therefore to have interjection from a staff of the Secretary at that level I think could be stultifying to the process.

Senator Dole. Dr. Sherman, you are aware of the statement of the Pharmaceutical Manufacturers Association, and the National Society for Medical Research, indicating the routine use of the LD-50 test is no longer necessary?

Dr. Sherman. Yes.

Senator **Dole**. So is it fair to say that we are in agreement, that there are areas where the number of painful experiments on animals can be reduced?

Dr. **Sherman**. I think this is an area of constant progress. Unfortunately, many of these tests, particularly in that area, testing as contrasted with research, are mandated. Therefore it's a problem in statute or regulation.

Senator **Dole**. Well, again I want to thank the panel for your thoughtful statements and consideration of the real problem. We will surely work out something.

Dr. Rackow and Dr. Derby.

As you are coming forward, I would hope we might be able to conclude our hearing by 11 o'clock. That may require you to summarize your statements, because I do have a couple of questions I would like to address and I have another commitment at 11. I don't see any of my colleagues showing up.

STATEMENT OF DR. HERBERT RACKOW, SCIENTISTS' GROUP FOR REFORM OF ANIMAL EXPERIMENTATION

Dr. **Rackow**. My name is Herbert Rackow, and my testimony is on behalf of the Scientists' Group for Reform of Animal Experimentation in favor of prompt enactment of S. 657.[1] I am a retired physician, a diplomate of the American Board of Anesthesiology and fellow of the American Academy of Pediatrics; I am professor emeritus, College of Physicians and Surgeons, Columbia University.

The provisions of S. 657 for adequate exercise and for appropriate pre- and post-surgical medical and nursing care are long overdue. From a humane standpoint, exercise and socialization outside the cage are important for the emotional as well as the physical well-being of an animal.

From a scientific standpoint, if the animal is to be used as a model for man, then medical and nursing care should be similar to that provided a human patient, modified only to be appropriate to the needs and to the humane treatment of the experimental animal.

No surgeon in his right mind would put a presurgical patient, healthy except for the local pathology requiring surgery, in bed for a few weeks before surgery and then, after surgery, restrict the patient to bed rest for a few months. Yet when animals are used for experimental surgery they are often confined to small cages for long periods of time. Changing this requires mostly a change in attitude. It should be possible to provide exercise and the necessary pre- and post-surgical care with existing staff.

The bill provides—page 4, line 13—that the Secretary shall promulgate standards for research facilities to insure that animal pain and distress are minimized. This clearly limits the authority of the Secretary to that area of animal use in research with which S. 657 is concerned, namely, animal pain and distress. It does not authorize judgments concerning the research itself.

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[1] See p. 77 for the prepared statement of Dr. Rackow.

The scope of the institutional animal studies committee is limited in the same way—page 6, lines 4 to 11. I do not think that progress in the medical and biological sciences depends upon inflicting unnecessary pain and distress on experimental animals.

These provisions address a legitimate concern; they are important and they should be retained as written.

The provision, page 7, line 11, that the animal studies committee report unacceptable conditions to the administrative representative of the research facility might be extended, in this committee's report, to provide that the animal studies committee report unacceptable conditions also to the director of animal care of the research facility. Similarly, employees should report violations—page 8, line 5—to the director of animal care as well as to the institutional animal studies committee. The director of animal care is likely to oversee animal care on a daily basis while the animal studies committee is not.

The provision, page 7, line 15, that the animal studies committee provide training sessions may have little meaning unless attendance by the scientists or their representatives, and by those involved in the actual care of experimental animals, is mandatory. Perhaps the report of this committee might point this out.

The provision, page 8, lines 14 to 25, that the Secretary establish an information service at the National Agricultural Library in cooperation with the National Library of Medicine should be an important contribution to accessibility of scientific literature in this area. Easy accessibility to information about alternative methods should reduce animal pain and distress.

The assurance-of-compliance provision, pages 9 and 10, and the following provision, page 10, that the Secretary promulgate standards of compliance, are excellent. My interpretation of the assurance against the use of paralytics without adequate anesthesia is that adequate anesthesia means continuous general anesthesia causing unconsciousness. I would like to suggest that this committee's report reflect this interpretation.

The establishment of an effective institutional animal studies committee is a key provision of S. 657. We know from past experience that NIH site committee inspections and USDA inspections can be inadequate to insure humane treatment of animals. In what way will the committee established by S. 657 be different? The crucial difference is that S. 657, for the first time, brings to the inspection committee an independent, unpaid member who is not affiliated with a research facility, has no conflict of interest, and whose prime responsibility is to the welfare of the animal subjects, not to the research facility, not to NIH, and not to USDA.

The effectiveness of S. 657 in insuring humane treatment of experimental animals will stand or fall on the quality and quantity of this kind of member. I hope that this committee's report will suggest that the research facilities seek the advice of humane organizations in the selection of this member, and that at least one-third of the total members of each animal studies committee be selected this way.

These actions would go a long way toward insuring that the animal studies committee has its intended effect.

Thank you.

Senator DOLE. Dr. Rackow, I will just ask you to comment on one point. Obviously, you feel, based on your last statement that lay people and scientists can work together to reduce pain and distress in experiments

Dr. RACKOW. Yes, I do. I think that the institutional review boards concerned in human experimentation work very well. I do not think that they have impeded the results of human experimentation in any way. I think that the institutional animal studies committee should work the same way, for the same reason.

Senator DOLE. Thank you very much. Dr. Derby.

STATEMENT OF DR. BENNETT DERBY, PROFESSOR, CLINICAL NEUROLOGY AND PATHOLOGY, NEW YORK UNIVERSITY

Dr. DERBY. Senator Dole, I know you have read this statement, which has been distributed, so I will highlight my highlights.[1]

I am here today representing certain humane groups and animal welfare organizations who have worked over a long period of time for this legislation. They are each submitting their own testimony for the record. I am also here as an individual speaking for myself, with a background in medical research.

The balance between the needs of the animal and the needs of legitimate research is precisely what the concern of the Congress is. S. 657, I think, achieves necessary forward moves better than any other available legislation to date. And the direction shows a true understanding of the need for further improvement.

Pain is a clinical consideration in animals just as in man, and it is totally appropriate that a clinical veterinarian be responsible in this area. It is an area which has nothing whatsoever to do with the peer-review process, and it has everything to do with animal comfort. Pain may not be able to be measured, but its presence can be identified, and you don't need subspecialty training to do that.

This bill provides an effective measure, not to be perfect and prevent all pain, but to prevent unnecessary pain, and this bill goes beyond the narrow timeframe of surgery into the whole stay of the animal and for the need for euthanasia.

The committee constitution which would involve a lay member is free to obtain as varied or as many consultations as it wants should there be any question of judgment. A particularly sensitive area exists in neurophysiology which requires special thought. Your committee has been provided with photographs of animals in a stereotactic holder, and this is an animal who is unable to move, unable to cry out, without general anesthesia.

This form of research is essential, if it is properly carried out and if it is seen to be necessary without alternative. Under these circumstances, adherence to procedural details, including careful consideration of whether or not there is an alternative to the lack of general anesthesia, is essential.

And I think there has been an unnecessary confusion about the word "methodology." That has nothing to do with research design, concepts, goal, or principles. Methodology is a word that I have interpreted, and perhaps it should be clarified by the legislation, to have to do with the testing itself, the procedures, the nitty-gritty, the technique. And the word methodology, as I have taken it, and on which this report of mine is based, has nothing to do with the province of the concept of research, interference with which I would fight like a bandit. That is important.

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[1] See p. 82 for the prepared statement of Dr. Derby.

S. 657 doesn't ask for any special money. It has become readily apparent that people who feel that such things as having enough animal keepers around and so forth are people who probably aren't doing it in the first place. The capital expenditure that might be required would not have been the result of S. 657; it would be a result of what was needed. The purpose of S. 657 isn't to create standards for care, after all; it is a provision to inspect them.

There has been the use of the word "certification." Much of this has been blind. As we have heard today, most sites already have a review committee; there is nothing new in that whatsoever. And I think that commonsense is the basic aim here. As an example, the requirement for exercise is little more than stating that animals should not spend their entire lives within a cage.

I think there could be a lot of controversy about how much is enough, and no disagreement at all that there is such a thing called cage paralysis.

So that the wind-down to the need for an impact study rings fairly hollow, since everybody is aware of the fact that there is a problem, and the credibility gap of standards versus effectuation of standards.

I think that any study program that simply dwells on how large the problem is or in which areas it might be larger than another, I find superfluous, given the precise and very skillfully drawn aims of the proposed legislation, S. 657.

Senator DOLE. Dr. Derby, thank you very much. On page 4 of your statement, you indicate fit animals result in obtaining more accurate physiological data which is more replicable with less wastage. Could you explain the term wastage?

Dr. DERBY. Well, if you buy a hundred, and you only get to work on about, say, 65 or 70, because the others died, that's wastage.

Now, it's well understood that there is a certain minimum of that: animals, like people, do die. Wastage is excess loss due to poor care. Whenever you have excess wastage, it immediately casts light on what is the base physiology of the animals you are actually using for the experiment.

So you save money, and you get better research.

Senator DOLE. I thank you both. Your statements in their entirety will be made a part of the record.

I would say to others who would like to submit statements, the record will remain open for a period of 10 days. We will also make—not reprint in the record—but will attach to the record—it won't be printed, it will cost too much money—the "Guide for the Care and Use of Laboratory Animals," published by NIH.

So with that we will conclude the hearing. I would hope that if somebody has any better idea on how we can resolve this without waiting 18 months I would like to know your suggestions. There is a lot of support for the efforts that have been undertaken by a number of groups and a number of people concerning S. 657, and we appreciate your help.

Thank you.

[Whereupon, at 11 a.m., the committee adjourned, subject to call of the Chair.]

APPENDIX

STATEMENT OF HON. ORRIN G. HATCH, A U.S. SENATOR FROM UTAH

I understand you have scheduled hearings on Wednesday, July 20, 1983, related to S. 657, amendments to the Animal Welfare Act to insure the proper treatment of laboratory animals. Please be assured that I share your concern that proper care be given laboratory animals.

For this reason, Senator Kennedy and I introduced S. 964, the Animal Research Study Act of 1983. This legislation is designed to provide a comprehensive assessment of the current status of the use of live animals in biomedical and behavorial research. In particular, S. 964 will provide for Congress information regarding the number of animals used in research, the status of laboratories with animal accreditation programs, activities of the Department of Health and Human Services in the area of laboratory animal research, and review currently existing State and Federal statutes and regulations governing the use of animals in research. In addition to the information required by this study, I have requested, by letter, a study by the Office of Technology Assessment (OTA) regarding the status and future of research methodologies providing alternatives to the use of animals. This study is scheduled to begin in September of this year.

Although your bill, S. 657, pertains to the care, treatment and use of laboratory animals in biomedical research and testing. I feel it is based on assumptions for which current and comprehensive data is not fully available. Therefore, I believe S. 964 is desirable and necessary before other legislation is considered.

As you may know, S. 964 was incorporated as Title III of S. 773, the Biomedical Research, Training, and Library Assistance Act Amendments of 1983, when we considered the bill in Executive Session on May 26, 1983. This bill was unanimously reported from the Committee and awaits consideration on the floor of the Senate.

I am deeply committed to the conduct of research under optimal scientific and ethical standards and therefore share your concern about reports of mistreatment and abuse of animals used in research. I would be pleased to work with you in implementing federal legislation to address these concerns but believe we can do this most appropriately and effectively when we have the information required in S. 964. Therefore, I respectfully suggest that you not proceed with action on S. 657 until we have the information that would be provided by the Animal Research Study Act and the Office of Technology Assessment.

STATEMENT OF BERT W. HAWKINS, ADMINISTRATOR, ANIMAL AND PLANT HEALTH INSPECTION SERVICE, U.S. DEPARTMENT OF AGRICULTURE

Mr. Chairman and members of the committee: I appreciate this opportunity to express the views of the Department of Agriculture on S. 657, a bill "To amend the Animal Welfare Act to ensure the proper treatment of laboratory animals."

Appearing with me are Dr. Kenneth Hook, Associate Deputy for Veterinary Services, and Dr. Richard Rissler, Assistant Director Animal Health Programs.

The Department of Agriculture [USDA], through the Animal and Plant Health Inspection Service [APHIS], administers the Animal Welfare Act. One of the objectives of the act is to ensure humane care and treatment of certain warmblooded animals intended for use in research facilities. APHIS is responsible for the registration and inspection of approximately 3,300 research facilities in the United States.

Mr. Chairman, the bill the committee is considering today expands the definition of "research facility" to include each Federal Department, Agency or instrumentality. This means that USDA would be required to register and inspect Federal laboratories.

Under current authorities, almost all State-owned or privately owned research facilities, which use animals for research, testing or experiments must register with

USDA. Registration and inspection are the means of assuring that laboratory animals have the necessary veterinary care and "creature comforts" of adequate housing, handling, sanitation, food, water, and protection against extremes of weather and temperature during research and when transported. While Federal laboratories are not required to register with USDA, they are required to comply with the same standards of care and treatment and reporting requirements established for State-owned or privately owned research facilities. Federal agencies, through internal systems, monitor compliance of Federal laboratories. Therefore, we question the need to include Federal laboratories under the definition of "research facility."

Also, we question the provisions of the bill which change the requirements for standards of veterinary care and "creature comforts" from "minimum" to "proper". This change would require us to develop standards considered to be "proper" for the different segments of the industry and various animal species covered by the act. The term "proper" would have to be qualified, that is, proper requirements with respect to the type of animal, the species, the use of the animal, its immediate environment, and other factors. The term "minimum" is more definitive and more enforceable in a court of law. In practice, requirements for proper care and treatment of animals used for purposes of research, exhibition, transportation, etc., can be met under current authorities.

Further, we do not favor adding "adequate exercise" as a required standard because it would be extremely difficult to determine what amount of exercise would be "adequate" for each of the various species. Our regulations require that the primary enclosure for each animal be properly constructed and maintained to allow the animal "adequate" space for freedom of movement in all directions. In addition, our inspectors are required to pay special attention to animals kept in small enclosures to ensure the space provided meets our requirements, unless the research protocol calls for restricted space.

Mr. Chairman, the law and regulations are designed to leave researchers free to conduct studies they consider necessary. However, these researchers must, wherever possible, use appropriate pain-relieving drugs during actual research or experimentation. In connection with this, research facilities and Federal laboratories must submit an annual report to the Secretary on the care and treatment of animals used in research. The report must indicate whether any painful experiments were conducted and when pain-relieving drugs were not used during painful experiments.

We believe that the determination as to whether an animal is suffering momentary pain or discomfort during actual research or experimentation should be a required element of professional judgment made by the trained doctors of veterinary medicine in charge of the research and researchers trained in other biomedical sciences. Even then, there would be a lack of uniformity concerning pain interpretation. Therefore, we object to the bill's definition of the term "direct use of conscious animals" which would require the Secretary of Agriculture to promulgate regulations establishing standards for momentary minor pain and discomfort for various animal species. Additionally, this requirement, coupled with the repeal of the prohibition against the Secretary of Agriculture regulating outlines, guidelines or performance of actual research or experimentation by a research facility, would place the Secretary in the position of regulating research projects of other Federal agencies.

Also, the bill mandates the establishment of an institutional animal studies committee, and requires each such committee to conduct inspections at least semiannually, of all animal study areas and facilities of the research facility. This committee must certify to the Secretary of Agriculture that these inspections took place, and notify, in writing, our Animal and Plant Health Inspection Service [APHIS] of an unacceptable conditions of animal care, treatment or methodology which were not included in the certification.

Mr. Chairman, inspections of research facilities, including oversight of animal research, is already provided by this Department through APHIS. To enhance coordination and effectiveness of these activities and at the same time avoid duplication of effects, we have implemented a Memorandum of Understanding with the Food and Drug Administration and the National Institutes of Health. Further, the requirement in the bill that each institutional animal studies committee file two certification reports each year with the Secretary of Agriculture and notify APHIS of any unacceptable conditions, would create unnecessary oversight procedures.

Our regulations and standards of animal care for registered research facilities are enforced through regular and unannounced inspections, action on alleged violations, and review of the annual reports on the appropriate use of pain-relieving drugs during experimentation of the animals.

Increased public interest in the humane care and treatment of laboratory animals prompted the Department to do an in-depth review of its enforcement of the Animal Welfare Act as it relates to research facilities. The review was directed toward determining whether inspection operations provided adequate assurances that laboratory animals are receiving appropriate care and treatment. As a result, we revised a number of our internal policy memoranda to provide more specific and uniform instructions for the veterinarians who actually conduct the inspections. Detailed written instructions have been developed on how to conduct inspections. To assure quality of inspections, we have established annual training sessions and intermediate training where needed, for all animal care personnel. Video tapes, slide presentations, and inspection workshops are used to reinforce the written instructions. Also, the Area Veterinarian-in-Charge [AVIC] has been made primarily responsible for the assignment of properly trained and committed animal care personnel considered to be capable of successfully implementing our authorities under the Animal Welfare Act.

Finally, we believe that the bill's provision for establishment of an information system on improved methods of animal experimentation at the National Agricultural Library can be achieved under current authorities.

Mr. Chairman, the Department strongly supports humane care and treatment of animals and commends the objective of this bill to ensure humane treatment, care and appropriate use of laboratory animals. However, for the reasons mentioned earlier, do not recommend enactment of S. 657.

STATEMENT OF WILLIAM F. RAUB, PH. D., DEPUTY DIRECTOR, EXTRAMURAL RESEARCH AND TRAINING, NATIONAL INSTITUTES OF HEALTH, PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH AND HUMAN SERVICES

I appreciate this opportunity to testify about the care and use of animals in research funded by the National Institutes of Health (NIH). As Deputy Director of the NIH for Extramural Research and Training, my primary responsibility is the body of policies and procedures applicable to the approximately 20,000 research grants and contracts that we award annually to medical schools, other institutions of higher education, not-for-profit research institutes, and research-oriented commercial organizations (both small and large businesses).

As you know, Mr. Chairman, my comments today for the most part will not deal directly with S.657. I will confine my remarks to selected topics that I believe will be helpful in relating S.657 and the Department of Agriculture (USDA) testimony about that bill to the specific context of biomedical research.

I emphasize at the outset, Mr. Chairman, that the NIH regards animal experimentation as both a legislative mandate and a moral imperative. Biomedical research is society's only realistic hope for significant and long-lasting improvements in human health; and we must recognize that scientists need to use laboratory animals. Virtually every major medical advance in this century was rooted deeply in animal experimentation, as can be ascertained by even cursory inquiry into the research advances that fuel the current progress against such disorders as leukemia, Parkinson's disease, diabetes, kidney disease, blindness, hepatitis, and heart disease. In the interest of brevity I will cite only two specific examples. First, the landmark discovery of insulin by Banting and Best in 1921 was possible only because of the research these scientists were doing with dogs; and that discovery alone has saved the lives of millions of people. The second example is the development of the hepatitis B vaccine, a major medical advance that would not have been possible without the use of chimpanzees. This legacy seems certain to be the prologue for the indefinite future, for we cannot envision now how the substantial momentum of current efforts to improve human health could be maintained, much less increased, without continued reliance on animal experimentation.

At the same time, Mr. Chairman, we feel an obligation as stewards of public funds and as scientists to promote appropriate use and proper care of laboratory animals. For several decades, the NIH has been mindful of public concerns about animal experimentation and has made a vigorous effort on behalf of animal welfare. We strive continually to avoid unnecessary animal experiments and experimental procedures. We also subscribe to the concept that, when animal experimentation is indicated, high quality animal care is required as much by good science as by good conscience. These views are manifest in long-standing activities directed toward ensuring the welfare of research animals. I will summarize those activities and then describe some recent initiatives.

The first substantive step in our award process generally is the technical merit review of research proposals, and it is at that point that our attention to the proposed use of animals begins. Reviewers are responsible for judging whether the nature and extent of the intended animal experimentation is justified. Executive secretaries of review groups must be sure that these issues are discussed and must record the outcome in the written summary of the review. Moreover, our program staff are expected to satisfy themselves that these matters have been dealt with fully and satisfactorily before they make an award. To facilitate implementation of these policies, we provide written instructions to reviewers and executive secretaries, and we instruct applicants for research grants to furnish as an integral part of their request a full description of their proposed use of verterbrate animals.

There can be no HHS award to any institution that does not have on file with NIH an acceptable statement of assurance, signed by a senior official of the institution, committing the institution to a satisfactory program of animal care and use. Also, we require each institution to have an animal care committee, with at least one veterinarian member, to assist in meeting that commitment. I will discuss the assurance process and the animal care committees in more detail later in my statement.

Finally, we have maintained a strong effort - both formally and informally - over the last several years to coordinate our activities with those of other Federal agencies having responsibilities related to laboratory animals. In particular, we have taken the lead with respect to several policy and planning issues related to nonhuman primates.

I now turn to some new activities. I am pleased to report specifically on five recent initiatives that we believe will make our traditionally strong efforts even more so.

The first noteworthy item is the Memorandum of Understanding, signed on April 11, 1983, between the USDA and the Department of Health and Human Services (HHS); I will provide a copy for inclusion in the record. Specifically, the Food and Drug Administration (FDA), the NIH, and the Animal and Plant Health Inspection Service (APHIS) of the USDA established through this Memorandum a system for information sharing to help all three entities carry out their respective roles more effectively. For example, from time to time the NIH has a need to know the results of USDA or FDA inspections of laboratory animal facilities that receive NIH funds and simultaneously fall within the regulatory purview of one or both of these agencies. Similarly, USDA and FDA inspectors sometimes can understand better the interactions between animal care practices and the scientific objectives of NIH-funded research when they have access to the expertise of NIH staff and advisors.

The second activity is the ongoing effort to update and refine the NIH Guide for the Care and Use of Laboratory Animals. First issued in 1963 and antedating even the Animal Welfare Act, this publication has been acclaimed widely by veterinarians, laboratory scientists, research administrators, and lay persons alike as the most authoritative guidance of its kind. In particular, the Guide is the cornerstone of administrative requirements governing the animal experimentation funded by NIH. The Guide also provides the conceptual and substantive framework for the activities of the American Association for the Accreditation of Laboratory Animal Care (AAALAC), a private organization whose efforts to foster excellent animal care in biomedical research settings are strongly endorsed by the NIH.

The Institute of Laboratory Animal Resources (ILAR) of the National Academy of Sciences is now at work, under an NIH contract, to revise the Guide as appropriate. The ILAR traditionally has played a central role in keeping the content of the Guide accurate and timely, and the current contract is intended to continue that practice. An important addition to the process this time was the NIH request that the ILAR seek broad public comment on the current version of the Guide. Accordingly, the ILAR held three widely announced and well-attended public meetings in Washington, Chicago, and San Francisco within the last several weeks. We are optimistic that this new dimension in the process of revising the Guide will do much to ensure that it is responsive to the many important perspectives that exist regarding what constitutes proper care and use of laboratory animals.

The third initiative involves a series of site visits this summer by NIH staff and advisors to a random sample of awardee institutions to assess their programs of animal care and use based on the statements of assurance I mentioned earlier. HHS policy requires that each grantee and contractor submit such an assurance in order to be eligible to receive HHS funds for laboratory animal research. For example, many institutions indicate that they are in full compliance with the Guide mentioned above; whereas others identify areas of partial compliance and their plans for eliminating those shortcomings. One way of demonstrating full compliance is through AAALAC accreditation of the institution's animal facilities. The NIH regards accreditation by AAALAC as the strongest form of assurance.

The assurance system is based on trust between the HHS and its awardees and, we believe, is fundamentally sound. However, in a few instances over the last several years, the NIH found awardees to be out of compliance with their assurances, and we came under severe criticism for not detecting and acting upon those breaches of trust sooner. The result was a threatened erosion in public confidence in our stewardship - a prospect we found unacceptable.

We therefore undertook a formal assessment of the assurance system. After developing a detailed site visit protocol with the aid of three AAALAC-accredited institutions in the Middle Atlantic region, we selected 10 non-

AAALAC-accredited awardees for review. The selection procedure was a random sample structured so that the institutions are well distributed with respect to both geography and size. The site visits include meetings with top administrative officials, the attending veterinarian(s), members of the animal care committee, and representative investigators, as well as tours of the animal facilities. The site visitors are NIH staff and non-Federal consultants with expertise in laboratory animal medicine and/or research.

We expect to complete the series of ten visits by October and to decide then whether- and, if so, in what form-to continue this initiative. With your permission, Mr. Chairman, I will submit for the record copies of recent public announcements about the site visits.

My fourth example, Mr. Chairman, relates to part of S.657--namely, that part which deals with the composition and functions of animal care committees within awardee institutions. As I mentioned earlier, we have required for many years that awardees engaged in laboratory animal research have animal care committees consisting of at least five members, one of whom must be a veterinarian. Recently, we have been exploring the nature and extent of additional guidance that might be appropriate with respect to these local committees. In particular, we believe there is considerable merit in the notion that these committees might include at least one non-scientist and at least one individual not employed by the institution. We plan to seek comment from the scientific community and general public on these and related matters during the coming fiscal year and then move accordingly to revise our policy statements.

Finally, I call to your attention a special effort to identify non-animal research methods deserving further development and evaluation. I refer specifically to the plans of our Division of Research Resources to sponsor a series of workshops focused on such biological systems as mammalian cell cultures, invertebrates, and microorganisms and on such physical science techniques as mathematical modelling and computer simulation. To the extent that the Division can identify new research and development opportunities in this area and foster the emergence of new concepts and methods, it ultimately could reduce our dependency on laboratory animals.

That concludes my report, Mr. Chairman. Thank you for including the NIH in this hearing. I will respond as best I can to any questions you or the other members may have about NIH policies or about the relationship of those policies to specific provisions of S.657.

STATEMENT OF JOHN P. JORDAN, PH. D., REPRESENTING AMERICAN INSTITUTE OF BIOLOGICAL SCIENCES

I am Dr. John Patrick Jordan, a research biochemist and director of the Colorado State University Experiment Station which is headquartered at Fort Collins, Colorado. I have served as an Animal Care Director.

Today I come before you as Chairman of the Public Responsibilities Committee of the American Institute of Biological Sciences, an organization composed of 30 biological societies whose amassed membership is more than 60,000.

As you can well understand, the biological scientists of the United States are very interested in the issue of animal welfare. The foundation of that interest is the belief in the absolute requirement that scientists must deal with experimental and demonstration animals in a humane manner based upon sound ethics.

Biologists have watched with considerable interest the progress of proposed legislation aimed at protecting laboratory animals from misuse. The AIBS's major points of emphasis focus on ethics of handling research animals, quality of research data, and an overall respect for life.

We are fearful that anti-science sentiments might prevail to the detriment of biological, medical, and veterinary research and training. We are concerned that some critics of live animal studies are unrealistically optimistic in their expectations concerning the usefulness of computer modeling, cell cultures, and other substitutes for live animals. As scientists, we are disturbed by an attitude which would prohibit "research duplication" since replicability by other investigators is our only means of verification.

As citizens and as individuals many biologists have been shocked and disappointed by the actions of a small minority of our colleagues who seem to lack compassion and respect for life. The well publicized actions of these few and the resulting public reaction have had the positive effect of stimulating increased awareness of animal welfare issues among biologists, institutions, and funding agencies.

The AIBS would encourage congressional initiatives to develop information concerning the extent of live animal procurement, handling, and use in the United States as well as funding support aimed at developing alternatives to the use of live animals. However, much work must still be done to perfect alternative methods of research, and we would caution against excessive redirection of current research funding.

Many laboratories that use live animals have long established guidelines for animal care and many have established Animal Care and Use Committees. While some biologists oppose the inclusion of "public representatives" on Animal Care and Use Committees in the belief that this will only lead to confrontation and delay, others believe that generally this requirement will benefit researchers because it offers them an opportunity to communicate to the general public the benefits resulting from live animal research and the high quality of care by most laboratories.

You may be interested to know that at Colorado State, the Animal Care Committee, which has reported to me for five years, has as its Executive Secretary the Animal Care Director for the University. That committee has been empowered by the Governing Board of Colorado State University, the State Board of Agriculture, to review proposals involving animals in experimentation. The Laboratory Animal Resource Service supervises and maintains facilities, not only for laboratory animals of a classic type (rats, mice, rabbits, etc.) but the director also has a university-wide responsibility in the area of equine, bovine, procine, and ovine species.

The National Institutes of Health animal guidelines are used as the basis for decisions made by the Animal Care Committee at CSU and the ethical issue of animal research is its cornerstone. The other cornerstone is quality research data, which inevitably requires the highest quality of animal care. None of us believes that a nutritional study can be interpreted if the animals are mired in the muck of filth and the results are complicated by extraneous diseases. These two cornerstones have been effective in moving quality animal care facilities to a markedly higher priority within the University. Two years ago, CSU had the privilege of dedicating a new $1.7 million laboratory animal facility.

At the American Institute of Biological Sciences, we feel the essential features of any legislation must provide for an opportunity for the general public to be informed regarding the extent to which our knowledge of all biology, including human biology, is dependent upon animal experimentation. We also need further study of the best methods of ensuring reasonable care amd treatment of animals; otherwise, the generation of quality research data and learning will not prevail.

The question before this committee today is whether legislation to assure that the desired results of reducing pain and meaningless use of animals in experimentation is both needed and has the potential for effectiveness. The Public Responsibilities Committee of AIBS feels strongly that any such legislation should place the burden of responsibility with the institution and not on a new army of federal inspectors. We further recommend that the monitorship of such a program take into account the difference between legitimate research organizations and process or production oriented laboratories.

We feel that the federal inspection should focus on the maintenance of quality records within institutions... records that will demonstrate an effective animal care program with appropriate day-to-day supervision. The inspection should also ensure that the general state of facilities is commensurate with animal care standards outlined by the National Institutes of Health in its "Guide for the Care and Use of Laboratory Animals."

Recogniting that, at this particular time, major public effort is for reducing federal rules, regulations and monitorship, prompts the AIBS to continue in its efforts to encourage institutional commitment by research organizations to embrace both ther philosophy and the specifics outlined in the NIH guide.

A couple of years ago, the AIBS adopted a statement regarding the use of animals in experimentation and I would like to read that statement, Mr. Chairman, with your indulgence.

> "Live animals have long been an important tool n the conduct of scientific research and education. In biomedical, agricultural, toxicological, behavioral, and other biological studies, intact animals perform a vital and irreplaceable function, often serving as models for man. No alternative procedures are known that permit the conduct of some critical kinds of research without live animals. The American Institute of Biological Sciences recognizes that live animals will continue to be a important research resource. The AIBS also recognizes that live animals make a meaningful contribution to the educational process. Study of animals in the laboratory enhances student sensitivity to, and understanding of, all living creatures.
>
> The use of animals mandates responsibility to provide quality care and humane treatment. The AIBS endorses the 'Principles of Animal Use' promulgated by the National Institutes of Health and the National Association of Biology Teachers'

> 'Guidelines for the Use of Live Animals at the Pre-university Level.' Organisms of the lowest phylum consistent with the knowledge to be gained should be used in research and study. Intrusive studies should be discouraged, especially below the intermediate college level. Educators should rely on demonstration and observation; other procedures deemed necessary should be used under the direct supervision of a qualified instructor. In all circumstances, scientists and educators must fulfill their moral responsibilities to give proper care and human treatment to the animals they use."

Thus, you should know, Mr. Chairman, that even without legislation, other groups will be pressing for a continued improvement and upgrading of facilities and techniques used in the handling of animals for research and demonstration. Further, we are interested in encouraging research relative to alternatives that may be effective and appropriate but lessen the need for invasive or hurtful protocols on live animals.

We do not feel that S 657, "Improved Standards for Laboratory Animals Act," would impose major hardships on most laboratories nor would it impede good research. Yet it would provide a logical approach to ensuring good quality humane care and treatment of laboratory animals.

We feel this bill is a much better vehicle for protecting animals and allowing good research than any other provisions under consideration because it would provide a logical approach to ensuring the care and treatment of laboratory animals by amending current provisions of the Animal Welfare Act, which already has established standards for entities involved in research requiring the use of animals.

Let me close by restating that the American Institute of Biological Sciences considers good care and humane treatment of animals essential to good research and good research is essential if we are to conquer disease and illness as well as provide plentiful, nutritious food supplies for tne world. Thus, if it is deemed that legislation is necessary to further these goals, then we could support the bill, S 657.

Thank you very much for allowing me to appear before you today to express our continuing concern for quality animal care and good research efforts that are needed to meet the needs of society.

STATEMENT OF DR. HERBERT RACKOW, REPRESENTING SCIENTISTS GROUP FOR REFORM OF ANIMAL EXPERIMENTATION, WHITESTONE, N.Y.

My name is Herbert Rackow. I am a retired physician, Diplomate of the American Board of Anesthesiology, Professor Emeritus of the College of Physicians and Surgeons, Columbia University and a Fellow of the American Academy of Pediatrics. My professional career was at the College of Physicians and Surgeons of Columbia University and at Babies' Hospital of the Columbia Presbyterian Medical Center. I was full time and did both clinical practice and research. My testimony is on behalf of the Scientists Group for Reform of Animal Experimentation and is in favor of prompt enactment of S.657.

I wish to quote a statement of the National Society for Medical Research: "If a Texas millionaire wanted to give his pet hound the world's finest care, he would be hard put to equal the kid gloves treatment which thousands of dogs receive today in modern animal research laboratories throughout the nation." This testimony was presented 21 years ago at Congressional hearings concerned with humane treatment of animals used for research. Yet no scientific organization, no university, no research facility has repudiated that statement. However, since then, representatives of the scientific community have become more sophisticated in their testimony, and have made 3 points that any regulatory changes to ensure more humane treatment of experimental animals would be 1) either impossibly expensive or 2) would bring medical progress to a grinding halt or 3) are unnecessary. These predictions are apparently not true for many European democracies.

These countries are not as nearly rich as the United States and have strictly enforced regulations far more humane than our own. These countries are able to conduct medical and biological research of top notch quality and even attract many of our best young scientists to their laboratories to complete their training. Many of our senior scientists go to these countries to spend their sabbatical years.

The provisions of S.657 for adequate exercise and for appropriate pre- and post surgical medical and nursing care would ensure more humane treatment of experimental animals and would also upgrade the standards of scientific methodology. From a humane standpoint exercise and socialization outside the cage are essential for the emotional as well as the physical well being of an animal. From a scientific standpoint, if the animals are to be used as a model for a human patient, then medical and nursing care must be similar to that provided a human patient modified only to be appropriate to the needs and to the humane treatment of the experimental animal. No surgeon in his right mind would put a vigorous healthy presurgical patient (healthy except for the local pathology requiring surgery) in bed for a few weeks before surgery and then after surgery restrict the patient to bed rest for a few months. Today because we know the great value of early ambulation, even elderly debilitated patients are taken out of bed as soon as possible after surgery, often on the first day post-op if only to sit in a chair. Yet when animals are used for experimental surgery, they are often confined to cages for long periods of time and the cages are too small to permit stretching in all directions. How long is a long period of time? NIH *Guidelines* state that short term confinement to cages is one to three months. If results of an experiment are to apply to man, it seems reasonable that conditions of pre- and postsurgical medical and nursing care similar to those provided for man must be provided for experimental animals. It should be possible to handle most, if not all of this care with existing staff. What we are concerned with is mainly a change in attitude.

The bill provides p.4 line 13 that the Secretary of Agriculture shall promulgate the standards for research facilities...*to ensure that animal pain and distress are minimized*. These words very clearly limit the authority of the Secretary to that area of animal use in research with which S.657 is concerned. Since it does not authorize judgments of the research itself, but is specifically limited to animal care, treatment and methodology *in order to* reduce *unnecessary* animal pain and distress, it is hard to understand any objection raised to this provision. I do not think that research progress in medicine and the biological sciences depends upon the infliction of *unnecessary* pain and distress in experimental animals. The provision addresses a legitimate concern. It is important and should be retained as written.

For the same reason as above, the institutional animal studies committee, p.6 lines 4-11, is properly concerned with the inspection of the research facility in that same limited area of animal care, treatment and methodology and in the condition of research animals... to ensure that pain and distress are minimized. This committee has no authority to evaluate other scientific aspects of the research.

The basic need for the institutional animal studies committee is very well described by Nordin in Whistleblowing in Biomedical Research 1981 (Superintendent of Documents U.S. Government Printing Office, Washington, D.C.). Sponsored jointly by the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, the American Association for the Advancement of Science, and Medicine in the Public Interest. I quote from page 35: "Researchers in a university setting are under pressure to produce research results and justify money for more research. Promotion, tenure, office and laboratory space and equipment, library resources, secretarial help, travel money, salary increases and other important professional requisites depend on research productivity. Simply put, there is a strong conflict of interest that may affect even the best of persons. For example, research shows that medical schools respond significantly to changes in demand from their major funding sources. As James Madison said in The Federalist, When men are as angels, government will no longer be needed. We still need IRB's.

"The next question is: Should the government be doing this regulating within the university? Are there not sufficient committees that already exist within the university structure? I think the answer is that the government must do it or see that it is done; the university system of internal governance that grants almost complete autonomy to departments and individual researchers may provide inadequate protection for the human subjects of research. For reasons outlined above, it is difficult even within each individual institution itself to determine what protections exist, let alone whether they are adequate."

These remarks concerned human experimental subjects. How much stronger is the need for protection when the subjects are animals who cannot speak for themselves!

The provision that the committee report unacceptable condition page 7, line 11 to the administrative representative of the research facility, might be expanded in report language to ensure that the director of animal care be informed promptly of these conditions so there is a minimum of delay in taking any needed action.

Similarly, if an employee reports a violation to the animal studies committee (page 8, line 5) the director of animal care should be told what is wrong immediately. The director of animal care is likely to oversee animal care on a daily basis while the institutional animal studies committee is not.

The provision page 7, line 15 that the institutional animal studies committee provide annual instruction or training sessions in humane practice of animal maintenance etc. might also receive comment in report language to avoid any possible misunderstanding. I interpret it to mean that the committee arrange for the courses but not necessarily do the teaching personally. I suggest that attendance by the scientists or their representatives and by those involved in the actual care of the experimental animals be mandatory. The research facility should provide the facilities for the sessions.

The subject material of the sessions, the humane practice of animal maintenance, the concept, availability and use of research or testing methods that minimize or eliminate the use of animals or limit pain or distress and the utilization of the information service at the National Agricultural Library to prevent unnecessary duplication of animal experimentation is very appropriate. The provisions p.8 lines 14-25 that the Secretary establish an information service at the National Agricultural Library in cooperation with the National Library of Medicine to provide information on improved methods of animal experimentation whould not only reduce animal suffering but should also be of great value to the scientific community. In the long run, it should also sharply reduce the financial cost of biological experimentation without interfering with the progress of science.

The assurance of compliance provision (f) pages 9 and 10 and the following provision (g) that the Secretary of Agriculture promulgate standards of compliance are excellent and should be enacted as written.

The establishment of an effective institutional animal studies committee is a key provision of S.657. We know from past experience that NIH site committee inspections and USDA inspections can be inadequate to ensure humane treatment of animals. In what way will the committee established by S.657 be different? The crucial difference is that for the first time S.657, p.5, line 10, brings to the inspection committee an independent, unpaid member who is not affiliated with the research facility, has no conflict of interest and whose prime responsibility is to the welfare of the animal subjects, not to the research facility, not to NIH and not to the USDA. The effectiveness of S.657 in ensuring humane treatment of research animals will stand or fall on the quality and quantity of this kind of member of the institutional animal studies committee.

Thank you for the opportunity to make this statement in support of S.657.

STATEMENT OF BENNETT DERBY, M.D., PROFESSOR, CLINICAL NEUROLOGY AND PATHOLOGY, NEW YORK UNIVERSITY

I am here today representing the humane groups and animal welfare organizations who have worked over a long period for this legislation. While each organization is submitting its own written testimony for the record, I have been requested to express their strong support for S.657 which, of course, continues to exempt farm animals and is focused solely on the animals used in biomedical research and testing.

As a physician with a background in medical research, I have been involved with the care and utilization of animals from which we learn so much, and this has made me aware that they are placed in our hands without defenses of their own. I am speaking for myself, too, concerning this important bill. My curriculum vitae is attached.

Balance between the protection of animals and the needs of legitimate research must be the concern of the Congress. S.657 achieves this balance and does it more effectively than any other proposed legislation. As an amendment to the Federal Animal Welfare Act, the bill builds on an established structure which has the support of both the scientific and the animal welfare communities. The contribution to the content of this legislation which you have made through the 1970 amendment, Senator Dole, is appreciated by all. Your new proposal shows a true understanding of the need for further improvement in the standards of the Act.

The extension of the law's provisions to research and testing procedures is essential to the sound functioning of the law. By providing for review and inspection by an animal studies committee appointed by each institution, it will minimize animal pain and distress without impeding research concept and design.

Pain is a clinical consideration in animals as well as in man.

It is completely appropriate that a veterinarian be responsible in this area, an area which has nothing to do with the peer review process (nowhere involved in this bill) and everything to do with animal comfort. Pain may not be measured, but its presence can be identified, and this bill is an effective measure to prevent it. S.657 thoughtfully goes beyond the narrow time frame of surgery in an experiment or test, and provides for the prevention of pain in the pre-operative and post-operative spheres, and for euthanasia without delay for animals suffering after the conclusion of the experiment.

A protective review similar to that for human experimentation is recommended for animals by the American College of Physicians. Although the animal studies committees under S.657 are mandated to confine their considerations to care, treatment, methodology and practices and may not enter into questions regarding purpose and design of experiments as the Human Institutional Review Boards do, they will provide a useful mechanism for thoughtful consideration of techniques and practices in cases where pain is thought to be integral to an experiment without a known alternative.

The committee is free to obtain as varied consultations as it wishes should there be a question of the need for judgement. A particularly sensitive area exists in neurophysiology which demands special thought. This is the performance of manipulated procedures within the central nervous system without general anesthesia on a paralyzed animal that can neither move nor cry out. Adherence to procedural details including careful consideration of whether or not there is an alternative to the lack of general anesthesia, is essential. The requirement that any federal award proposal includes "in its justification of the research, the details of any procedure likely to produce pain or distress in an experimental animal and demonstrates that the principal investigator has considered possible alternative methods to any such procedure" is valuable in its stimulation of scientific thought.

S.657 does not ask for outlay of funds for special facilities, or for specialized personnel, but only requires those appropriate for good animal care and treatment. This bill does ask for common sense. It would not require anesthesiologists, registered nurses or intensive care units, but would require that surgery not be done on a Friday afternoon, leaving unconscious animals to recover alone and without care. S.657 does not add the requirement of a veterinary consultant, who is, after all already provided for, but does permit application of his clinical expertise to details of procedure well within his province. This legislation requires no burden of administrative expense, but provides for committee membership, inspection, and record keeping which may be carried out by existing staff and by the unpaid outside committee member representing community concerns for the welfare of the animal subjects. This is making the best use of time, not calling for expenditure of money. Requirement for exercise is little more than stating that animals should not spend their entire lives within a cage, and, further, that fit animals result in obtaining more accurate physiological data which is more replicable, with less "wastage."

No change is required by S.657 in good animal care. It simply provides for proper inspection to insure good animal care.

The suggestion for an "impact study" with which, in theory, no one might quarrel if focused on a new technology, here would only encourage delay in making decisions on matters already universally accepted.

Those who express concern about the need for extra funds to provide exercise, perioperative care and proper animal housing are, in effect, admitting that at present they are providing none of these and regard them as "improvements."

There are also those who agree that the institutional animal studies committee should be responsible for total animal care and treatment, yet would somehow wish that it not apply to research or testing practices. It is important to realize that general care of the animal cannot be separated from the care and treatment of the animal during an experiment, particularly since this is the purpose for which the animal is there, and when this is obviously the time when maximum pain and suffering is most likely to ensue, and the maximum safeguard is necessary.

A word is in order emphasizing the role of animal care technicians. It is they who spend by far the most time with the animals, before, during and after procedures, often making observations for experimental data. Because the veterinarian and the investigator are in and out of the animal facility, the responsibility for animal welfare falls chiefly on the care technician.

This duty is properly acknowledged by S.657 by providing for reports of violations directly to the animal studies committee by any employee. It is difficult to see how objection can be made to this provision, which acts for the animal and for the institution within a framework established just for this purpose. Until this legislation is passed, employees cannot reasonably be expected to risk their jobs by reporting violations of law to existing institutional committees. Yet these committees cannot fail to benefit from the feedback of day-to-day information, and, in turn, the institution is unlikely to be subjected to the sensationalism of reports to press or others outside the institution if it learns promptly of any misconduct or neglect and takes action to correct or prevent it. For the institution to be kept adequately informed, employees must be protected from the threat of personal criticism and the threat of job loss.

S.657 points the way to ground not previously broken in legislation, that of recognition of the value of formal study of alternatives to the use of animals in biological determinations. Techniques using microbe organisms or mammalian cell systems are well known, but their applicability to projects and tests hitherto using whole animals has not been fully explored.

Computerization of work done in this area, and in whole animal work as well, will provide a ready reference to investigators, serving to prevent unintended duplication and as a bank for ideas. This work has not yet been adequately addressed. For example, the surprising relative lack of use of knowledge of natural carcinogenesis is beginning to emerge in reconsideration of tumor incidence in animal groups exposed to administered substances. Provision of such information, made immediately available by computer by the National Agricultural Library in cooperation with the National Library of Medicine, can accelerate productive research and reduce excess tests. At a modest cost, the information center which S.657 would establish at the National Agricultural Library, can be expected to provide important economic benefits to the government in coming years, not only by preventing unintended repetition of identical tests by different government agencies such as the Interagency Regulatory Liaison Group has found, but because alternative methods, which tend to be less expensive than animal tests, will be more commonly used as information on them is more widely disseminated and further research and development ensues.

We warmly encourage this distinguished committee to approve S.657 with its benefits both for animals and for better research. It deserves enactment without delay.

TESTIMONY OF

THE AMERICAN PSYCHOLOGICAL ASSOCIATION

and

THE ASSOCIATION FOR THE ADVANCEMENT OF PSYCHOLOGY

SUMMARY

- The American Psychological Association and the Association for the Advancement of Psychology recommend to the Senate that, before any animal research legislation is enacted, a study be conducted as proposed by S. 964, The Animal Welfare in Research Act. We believe it is necessary to address the numerous unanswered questions surrounding the use of animals in research in order to make effective and appropriate policy decisions in this area.

- With regard to S. 657, we believe that many provisions in S. 657 would increase the regulatory burden for researchers without necessarily improving animal welfare, and that S. 657 poses particular problems for behavioral research, which often cannot use alternative research subjects.

Thank you for the opportunity to comment on S. 657, the "Improved Standards for Laboratory Animals Act" (Dole, R-KN). A substantial portion of the 72,000 members of the American Psychological Association and the Association for the Advancement of Psychology are behavioral researchers whose studies involve animals.

The provisions of S. 657 affect the full range of animal experimentation from medical vivisection, to psychological observation of animals, to experiments in animal husbandry. While we are in full agreement with the bill's stated purpose — "to ensure the proper treatment of laboratory animals" — we are concerned that some of the mechanisms proposed in S. 657

would create expensive and unnecessary bureaucratic interference in a wide range of animal research programs in hospitals, university research facilities and agriculture experimental programs.

The American psychological community concurs with the general objectives of the proposed animal research legislation. However, we are concerned that there is insufficient information on which to judge whether the mechanisms set forth in this legislation will have the desired results. We believe it is essential to assess the impact of these bills on productive research that is of critical importance to human welfare as well as their impact on animal welfare.

One particular concern for behavioral researchers is the fact that alternative methods of studying behavior for the most part are not feasible. Studying behavior requires studying live animals. Restrictions on the use of human subjects in research compel the use of other animals. The quality and momentum of this research have profound implications for human health and well-being.

Current research methods are not immune to improvement or change, but there must be a sound basis for rejecting them. The fact that alternatives are not now being used en masse does not signal a lack of awareness or sensitivity on the part of the research community. It may well reflect the necessarily slow process of developing such alternatives.

We believe that legislation such as S. 657 will not be effective unless it is based on something more than assumptions about what will or will not improve the care and welfare of laboratory animals. A study, such as that proposed in S. 964, the Animal Welfare in Research Act, will produce accurate information about the number and type of animals being used, and about existing administrative and research practices that affect their welfare. Only with this information will the most effective and appropriate policies and legislative mechanisms be developed for animal research.

Our comments on S. 657 follow.

Alternatives to the Use of Animals

In several instances, S. 657 promotes the use of alternatives methods of research or alternative research subjects. We support the objective of minimizing the number of animals being used, and minimizing any discomfort experienced by animals that are used. However, the emphasis on alternatives poses a problem for behavioral science in particular because alternatives are not as readily available for the study of behavior as they may be in other areas of science.

Tissue cultures, computers and radioimmunoassays are often suggested as replacements for animals. We believe that many researchers in a variety of disciplines would prefer to use these adjunct methods, but substitutes such as laboratory cultures of cells, while useful for certain biological and medical tests, do not develop arthritis, heart disease, multiple sclerosis, mental disorders or drug addiction. Tissue cultures cannot be used to study the interactions or behavior of body organs — for example, the effects of cardiovascular changes on brain function or kidney physiology. It is virtually impossible to study the behavior of a whole organism through the use of alternatives.

Despite these difficulties, behavioral as well as biomedical researchers are in active pursuit of alternatives to using laboratory animals. Alternatives are sought as a matter of routine in research, and their use is stressed whenever possible. However, this legislation offers little protection for research that cannot use alternatives to animals. Our concern is that such research would be subject to unnecessary delays or even unjustified rejection in federal review and funding processes. Problems caused by the demand for alternatives would be magnified for behavioral science, where, as noted above, fewer research alternatives are available.

Animal Studies Committees

There is a real need for a national study commission on the use of animals in research. Such a study could examine current practices in animal research, examine and disseminate the latest developments in substitute methodology, acquaint the research population with alternative methods, evaluate proposals for uniform national standards and, in general, provide much needed data about the care, costs and benefits of using animals in research. Without such a foundation, the animal studies committee, as proposed in S. 657, will be repetitious, flooding the research field with numerous similar, often contradicting, rulings and induce increased abiguity and fewer objective criteria for decision making in the research community.

The proposal to require animal studies committees at research institutions in large part would legislate what is already current practice at many, if not most, institutions. The establishment of animal review committees is not a concern per se. Many research facilities already have institutional committees that are charged with monitoring the care and use of laboratory animals. However, there are several problems inherent in creating a legislative mandate for such committees. For example S. 657 would create an inflexible role for the committees, ignoring the likelihood that different research programs and facilities have differing requirements and capabilities. Further, it is likely that this provision of S. 657 would increase the paperwork for research facilities and the federal agencies to which research institutions report, and could divert financial, administrative and personnel resources from supporting and conducting actual research.

With regard to the composition of the animal studies committees, we believe that the required participation of community representatives and veterinarians, while well intended, could cause an undesirable shift in emphasis away from overall research concerns -- but not necessarily in the direction of animal welfare -- and could place less qualified individuals in the position of reviewing research.

Many of the conditions to be addressed by the animal studies committees -- such as assessing comfort or distress -- are behavioral in nature. For example, consider the fact that some species have different environmental needs. One type of primate may require a cage that allows vertical movement while another may require a horizontal layout. Without knowing this, animal studies committee members may simply evaluate environmental conditions on quantitative bases, and in this instance would look only at the number of square or cubic feet per animal without considering the cage layout. It is difficult to imagine that inclusion of a veterinarian or lay person on an animal studies committee would guarantee the committee's sensitivity to these type of requirements, which are overwhelmingly behavioral in nature.

Another consideration is whether a requirement that the committee must include individuals to represent specific aspects of animal welfare would create certain procedural problems. For example, would the number and frequency of meetings depend upon whether those persons could attend? If they were not in attendance, would action taken by the committee be legitimate? Could non-attendance at meetings be used to place the institution in a position of non-compliance with the legislation, and thus ineligible to receive federal funding? These questions raise serious doubts about mandating representatives on the committee.

As a minimum, the structure and effectiveness of existing animal care committees should be studied before being locked into legislation. If it is determined that specific members of the committee will be responsible for specific aspects of animal care -- such as requiring that a veterinarian be on the committee in order to ensure the clinical care of animals -- then we would strongly urge that an individual scientifically trained in animal behavior also be required so that the psychological and behavioral needs of the animals will be adequately and appropriately monitored.

Statement of Assurances

In current practice, federal research proposals are required to include a number of the justifications and assurances called for in S. 657. However, this bill would also require additional items which are not necessarily relevant to scientific merit or animal welfare, but which would constitute an additional burden on applicants seeking research support.

Proposals for studies involving animals already are required by the research review system to provide detailed information about experimental procedures and to justify the selection of a particular methodology. A bibliography of relevant research, including research using alternatives, is also required.

Consultation with a doctor of veterinary medicine is not currently required and could pose a problem in two respects. Such consultation would increase the cost of submitting research proposals, particularly for smaller institutions or others that might not have routine access to veterinarians. The other issue is that an assumption is being made about the effect of including a veterinarian in research planning. Specifically, it is assumed that the presence of a veterinarian will automatically enhance or ensure animal welfare. This is not necessarily the case. Rather, this assumption raises questions about whether the training and education of veterinarians qualifies them to be involved in research planning and other activities as indicated in S. 657. Again, our concern is that this sort of information be in hand before legislation such as S. 657 is enacted.

In sum, the requirements for justifications and assurances for the most part do not appear to establish new practices of care and use for laboratory animals. These provisions do, however, constitute a regulatory burden for research. Further, they could be restrictive by legislating the structure of research proposals. An equally important consideration is that these provisions are not necessarily going to enhance animal welfare. Hence, we believe that neither research nor improved care and use of animals will be well served by these requirements in S. 657.

Funding

A final concern is that, without additional funds to implement the provisions of S. 657 or other animal research legislation, the net effect of such legislation will be symbolic rather than substantive. We believe that Congress would be more willing to provide funds for animal research legislation if it is demonstrated that such legislation is based on accurate data and would establish the most appropriate mechanisms. We believe it is possible and desirable to improve animal welfare without jeopardizing progress in research, but that this balance will not occur without further study.

Restatement of Summary Points

- We recommend to the Senate that, before any animal research legislation is enacted, a study be conducted, such as the one proposed in S. 964. The Animal Welfare in Research Act, to address the numerous unanswered questions that surround the use of animals in research.
- With regard to S. 657, the Improved Standards for Laboratory Animals Act, there are a number of concerns regarding the bill's impact on research in general and on behavioral research in particular. Briefly, those concerns are:
    1. Several provisions in S. 657 are based on assumptions rather than facts.
    2. Alternatives to the use of animals are difficult to find in the study of behavior, so the emphasis on alternatives in S. 657 may have a particularly adverse consequences for behavioral research.
    3. Several provisions in S. 657 pose a regulatory burden for research without assuring improvement in animal welfare.
    4. The fact that no funding is included in S. 657 means that the entire financial burden would fall on researchers, and would divert resources from direct support of doing research.

Again, we appreciate the opportunity to make these comments and would be pleased to provide further information or answer any questions Members of this Committee might have.

STATEMENT OF EMILY F. GLEOCKLER, PRESIDENT, HUMANE INFORMATION SERVICES, INC., ST. PETERSBURG, FLA.

Humane Information Services and all our members across the United States who for many years have supported efforts to alleviate the suffering of laboratory animals urge your prompt and favorable action on S. 657.

S. 657 is well designed not to hurt, but to help, biomedical research. This is constructive, not destructive, legislation. It will do a great deal to improve the quality and the effectiveness of research, and at the same time it will eliminate a large part of the cruelties now practiced on living animals.

We are not an antivivisectionist group. However, we respect the views of those who are antivivisectionists. They believe that no possible benefits accruing to people from research involving cruelty to animals can constitute a moral justification for such cruelty. With this, we would agree.

Civilized people have long since decided that the immediate benefits of barbaric practices to those who engage in them do not justify their use. They recognize, also, that the moral degeneration which is an inevitable product of such practices in the long run will offset the assumed benefits. To be consistent, they must agree that possible small additions to medical knowledge or even greater benefits to the human race should not be achieved at the expense of morally unjustified cruelties to lesser forms of life.

The tremendous increase in public concern for the environment, ecology, conservation and wildlife has been a major social phenomenon of the past several decades. This concern has spread to cover a much wider area of public recognition of social responsibility for civilized treatment of all forms of life, including domesticated as well as wild animals. At last it is recognized that preoccupation with the problems of human welfare does not justify ignoring the problems of animal welfare. Rather, the two are tied together with so many inextricable bonds that they could not be separated even if we tried.

So, it will no longer serve to defend unnecessary suffering by laboratory animals because it is part of a broad effort to improve public health and save human lives. The public, to a constantly increasing extent, wants to know how and why some particular source of animal suffering is required to serve some socially desirable purpose, and whether or not the end justifies the means.

The proposed legislation will no doubt be opposed by statements that scientists are humane, that the professional organizations are acting to prevent cruelty, and that legislation is therefore unnecessary. Certainly there are many humane men and women among scientists. But, as in any group, there also are those just the opposite. A law casts no reflection on the moral majority; it is necessary because there exists an immoral minority.

Can any informed scientist deny the use in some laboratories of curare and its chemical equivalents, in preparing animals for painful uses? These preparations only immobilize the animal, without dulling pain perception. They are a convenience, not an anesthetic or a substitute for anesthesia. Can any informed scientist deny that his peers in various specialties disagree over the need for using unanesthetized animals for certain experiments? Can any informed scientist deny that animals have been dumped into cages after major operations, and then left to gradually expire or recover in pain and discomfort, without any genuine need for post-operative observation, unnecessarily prolonging the life and suffering of the animals? Can anyone who has visited or worked in laboratories claim that all of them give post-operative care which would be required practice in any good veterinary hospital? Can any informed and humane-minded scientist who has had much experience in general-purpose animal-using laboratories deny that he or she has observed many instances of animal usage of which he highly disapproves, but has failed to speak up against because of the peculiar code of ethics which forbids one scientist to criticize another? Has any qualified scientist with a background of training in principles of experimental design and statistical methods failed to note work by fellow scientists which grossly violated these principles, dooming the "research" to non-significance even before it was undertaken, without making any effort to question the propriety of permitting the suffering of countless animals in such futile efforts to continue?

How many biomedical scientists have even read the highly professional and authentic textbook, *Principles of Humane Experimental Technique*, by Russell and Burch, of Great Britain? Although this book was published in 1959, is it not true that many of the practical and thoroughly scientific more humane procedures it suggests have yet to be put into general use?

An authentic random sample drawn by independent research analysts of articles from *Index Medicus* reporting on research involving experimental animals disclosed that 74.6 percent of the experiments could have, by use of proper statistical design, employed reduced numbers of animals with essentially no loss in statistical significance. Only 4 percent were judged to have been both well analyzed and well designed.

When one considers the great amount of totally unnecessary animal suffering represented by this misuse of experimental design and analytical procedures, not to mention the great waste of professional time and funds, can the humane societies be blamed for urging the scientific community to take internal steps to at least have some competent review of proposed projects before millions of animals are subjected to unnecessary suffering in these experiments?

Of all matters related to the use of animals in biomedical laboratories, by far the most sensitive is the freedom of researchers to plan and conduct their experiments without outside hindrance of any kind. But does this mean that the researchers should continue to be permitted to plan and do their work without any kind of effective review by their peers, with a view to making procedural suggestions designed to improve the prospective quality of the results, which incidentally would also lead to reduced animal usage? Are there not so many potential uses of available funds for biomedical research of real benefit to the public, which must go unfunded, that those charged with supervision of the research should stand by apathetically while animals are used by the millions in conducting projects of which only 4 percent are judged to have been both well analyzed and well designed?

Can any reasonable scientist feel that he is fair, and speaking in the best interests of biomedical research, when he categorizes all humanitarians concerned with these matters as antivivisectionists and crackpots?

Can there be any doubt, in the face of factual and scientifically unbiased answers to the series of questions that have been posed above, all falling within the general field of "refinement" of animal experiments, that it is high time that the researchers give some hard thought to what can be done, internally and by voluntary effort, to correct these conditions which many scientists, as well as humanitarians, have acknowledged cry out to high heaven for correction?

Numerous pioneering investigations by scientists properly trained in research techniques have pointed to the very promising potentials of experimental techniques not involving, or permitting a significant reduction in, the use of live vertebrate animals as biological models.

The papers reporting these findings were not prepared by antivivisectionists or "humane nuts," but by eminent and qualified scientists. True, those opposed to the use of animals in laboratories have seized on these scientific reports, which may have been frequently quoted or interpreted without reference to context or qualifications, as "evidence" that all or nearly all uses of animals in laboratories could be eliminated without significantly reducing the benefits of biomedical research and drug testing. But does this misinterpretation by laymen serve as an excuse for the researchers, many of whom, it must be admitted, are no more competent in the methodological specialties involved than are the over-enthusiastic humanitarians, to ignore or downgrade the potentialities of replacement?

One would think that the indications of these pioneering efforts would lead research administrators to insist that those given funds to use in research should make every reasonable effort to check with other scientists better trained in these newer techniques, to see if they are overlooking possibilities to accomplish more by using fewer animals and lesser funds. And it would seem completely reasonable to expect that university training for those preparing for biomedical research should include greater emphasis on the scientific disciplines required in the utilization of these techniques.

We cannot fault any of the provisions of S. 657. They represent some of the solutions which for many years we have endorsed. We believe S. 657 will bring us much closer to our objectives of eliminating unnecessary pain and distress for the millions of animals annually that give their lives for our benefit, of improving research and testing in our country, and of utilizing government funds more efficiently.

Statement of

The Cosmetic, Toiletry and Fragrance Association

The Cosmetic, Toiletry and Fragrance Association, Inc. (CTFA) is the national trade association representing the cosmetic, toiletry, and fragrance industry. CTFA has an active membership of more than 240 companies that manufacture or distribute approximately ninety percent of the finished cosmetic products marketed in the United States. In addition, CTFA includes more than 220 associate member companies from related industries, such as manufacturers of cosmetic raw materials, and testing laboratories. Many CTFA members utilize animal testing techniques at some time to satisfy safety substantiation requirements. CTFA therefore has an important interest in S. 657, "Improved Standards for Laboratory Animals Act."

CTFA agrees that animals used in testing should be treated humanely. In fact, animals that are used for testing by the cosmetic industry are treated humanely in accordance with the Animal Welfare Act, 7 U.S.C. §2131, and regulations promulgated under it by the U.S. Department of Agriculture, 9 C.F.R. Part 3, which prescribe requirements to ensure that test animals do not needlessly suffer either physical or emotional trauma. For example, the regulations include requirements for temperatures, enclosures, feeding, veterinary care, for use of anesthetics and analgesics where appropriate, and for separation by species where necessary. The government routinely inspects laboratories used for animal testing, receives reports from these facilities, and investigates reports of alleged violations. To the extent that S. 657 empowers the Secretary of Agriculture to promulgate comprehensive animal care standards for research facilities, e.g., Section 4(b) and (c), the bill is unnecessary, as the Secretary already possesses these powers. Nevertheless, CTFA does not object to these provisions.

However, CTFA believes that before any new legislation is considered, a comprehensive study of the animal care and testing issue should be conducted to obtain additional information on these issues and to consider whether legislation of this type is the best avenue to accomplish the goal of improved animal care.

For example, CTFA approves the study approach in S. 964, "Animal Welfare in Research Study Act of 1983," introduced by Senators Hatch and Kennedy. The study described in S. 964 would investigate the current status of animals in research, existing federal and state laws governing use of animals in research, and exploration of alternatives to animal research. Existing information would be gathered and synthesized to determine whether new legislation is truly warranted.

Many sources of information are available. For example, CTFA has been in the forefront of development of alternatives to animal research, through its establishment in 1981 of the Johns Hopkins Center for Alternatives to Animal Testing. CTFA would be happy to provide full information about the program as part of a study.

CTFA also has specific objections to S. 657 that center on the provisions covering institutional animal studies committees.

Section 4(d) of the bill provides that each research facility shall be required to establish an institutional animal studies committee to consist of "not fewer than three members...[who] shall possess sufficient expertise to assess the appropriateness of animal care and treatment in experimental research." Further, of the members of the committee:

> (ii) at least one member shall not be affiliated with the research facility and shall be primarily responsible for representing community concerns regarding the welfare of animal subjects (such member shall provide adequate assurances that he or she will not release any trade secrets or confidential information of the research facility...

CTFA believes that including an "unaffiliated community representative" in a laboratory setting is an unworkable situation, both from the standpoint of the laboratory and from the standpoint of the unaffiliated representative.

A key problem with requiring an unaffiliated member to serve on a research facility's animal studies committee is that an individual who is not familiar with the overall research goals and other legitimate concerns of a company, may have difficulty appreciating the need for a particular study.

While it may be useful to have an individual with some distance from the daily research activities involved in animal care issues, a non-employee could have a chilling effect on important research.

Many companies already utilize the animal study committee approach on an in-house basis. Committee members are, as practicable, selected from other parts of the company and are removed from day-to-day lab activities to assure objectivity in animal care committee deliberations. However, because these individuals are company employees, they have an understanding of overall research goals, they can be called upon on short notice for committee meetings, and they can be entrusted with trade secrets and other confidential material that may be part of the research plan (see pages 5-6, below).

On a more practical level, the selection of a suitable candidate to serve as an "unaffiliated community representative" on an animal studies committee can be ~~expected to present many~~ important practical difficulties. The bill specifies, properly, that all committee members "shall possess sufficient expertise to assess the appropriateness of animal care and treatment in experimental research." However, there are likely to be few individuals in a community who possess such expertise and who would be willing to serve on a committee. A community veterinarian, for example, may possess the requisite expertise, but it is highly uncertain that a practicing veterinarian would be willing to devote the time necessary to participate in an institutional animal studies committee. Experience with in-house animal care committees that now exist in many company laboratories shows that they generally meet at least once a month, and that their work can be quite extensive. A community veterinarian would understandably be reluctant to take time from his or her practice to participate on a company's animal studies committee. (The bill does not say whether there will be compensation for the unaffiliated community representative, so it would appear the candidate is expected to be a volunteer. If the individual is paid for his or her services by the laboratory, he/she could be subject to charges of conflict of interest.) This raises the further question of whether new research must stop until such a person can participate.

These problems are compounded when one considers that there may be several animal research facilities in a geographical location, all requiring unaffiliated community representatives to serve on their animal studies committees.

In addition, research decisions often must be made quickly, and an animal studies committee may need to be convened on short notice. An unaffiliated representative with his or her own business schedule might not be readily available for committee deliberations on short notice. If the press of company business demands that the committee meet without the unaffiliated member to consider the research, the research facility could be subject to unwarranted criticism from, e.g., animal rights groups who are philosophically opposed to use of animals in research generally.

A related question, not addressed in the bill, is what constitutes a quorum for a committee. In common practice, two members of a three member committee would constitute a quorum, for example. But it is not apparent whether the quorum should require the presence of the unaffiliated member.

Another industry concern with an unaffiliated community representative serving on a company animal studies committee is protection of trade secret and confidential information. The bill states that the unaffiliated member shall provide adequate assurances "that he or she will not release any trade secrets or confidential information of the research facility." Section 4(d). A "paper" assurance of this nature is simply not a sufficient inhibition against disclosure. Trade secrets and confidential information of a company are valuable property rights and therefore are entitled to the utmost protection. Federal law makes it a criminal offense for a government employee to disclose, to the extent not specifically authorized by law, certain confidential information submitted to the government. 18 U.S.C. §1905. Private individuals with forced access to trade secret or other confidential business information should be subject to the same sanctions. A company deserves a meaningful assurance that its secrets will be protected. Furthermore, the bill should provide for civil damages if an unaffiliated representative releases trade secret information and thereby injures a company. (CTFA is mindful that such provisions could discourage individuals from serving on a committee, and believes this is a further demonstration of the unworkability of including an unaffiliated representative in a company's laboratory setting.)

In conclusion, CTFA agrees that animals used in research should be treated humanely. CTFA believes that before any new legislation is considered, it would be prudent to conduct a comprehensive study of the animal testing issue. CTFA would be happy to lend its assistance in the area of programs to develop alternatives to animal testing.

CTFA members who perform research using animals adhere to the requirements of the existing Animal Welfare Act and regulations under it. Many companies have in-house animal care committees to assure that animals are humanely treated, and these committees generally include company employees who are not involved in daily research activities, to assure their objectivity. Practical and legal considerations demonstrate that including an unaffiliated community representative on an animal studies committee is not feasible.

Thank you for your consideration of our views.

STATEMENT OF STEVE KOPPERUD, LEGISLATIVE DIRECTOR
AMERICAN FEED MANUFACTURERS ASSOCIATION

The American Feed Manufacturers Association (AFMA) appreciates the opportunity to express its views on S. 657, a bill to amend the Animal Welfare Act to ensure the proper treatment of laboratory animals. For 75 years, AFMA has been the national trade association representing the nation's feed manufacturers. Members of the association produce more than 70% of the primary formula livestock and poultry feed sold in the U.S. In addition, some of AFMA's more than 650 members raise large numbers of food producing animals.

AFMA has a long history of commitment to the proper treatment of all animals. In September, 1981, the Association's Board of Directors formalized that commitment in an official position on the welfare of animals, the essence of which is that "AFMA is committed to the humane and compassionate care of all animals."

One of the stated goals of this legislation is to encourage the development of alternative methods to animal use in laboratory experiments. This is laudable, and AFMA shares Sen. Dole's hope that these methods are soon in coming and will prove to be practicable substitutes for current methods. However, alternatives such as computer models are likely several years away from general acceptance as accurate laboratory indicators. In the meantime, animal experimentation continues to be the most viable method for long-term research development.

To quote Dr. William F. Raub, deputy director of extramural research and training for the National Institutes of Health, in testimony on S. 657 before the Senate Agriculture Committee:

"Biomedical research is society's only realistic hope for significant and long-lasting improvements in human health; we must recognize that scientists need to use laboratory animals. Virtually every major medical advance in this century was deeply rooted in animal experimentation."

AFMA has reviewed S. 657, and while we commend the motivation behind this legislation, we question the need for this bill at this time.

The legislation appears to be premature. Implicit in S. 657 is the assumption that there is a general disregard on the part of laboratory practitioners for the welfare of their animal subjects. This has been fostered in great part by well-meant, albeit theoretical, accusations of abuse by representatives of animal welfare/rights organizations. We doubt this assumption is correct.

In absence of verifiable evidence to support these accusations--similar to the unfounded accusations made in recent years against modern farm animal production--AFMA has reacted favorably to S. 964, introduced by Sen. Orrin Hatch and Sen. Edward M. Kennedy, and now an amendment to the reauthorization legislation for the National Institutes of Health. This language calls for a comprehensive 18-month study of standards and care applicable to laboratory animals used in federal research projects. It is necessary to know if and to what extent abuse or maltreatment exists before legislating to correct an alleged situation.

Secondly, from AFMA's review of S. 657 it appears that statutory authority currently exists under the Animal Welfare Act to implement many of the recommendations included in this legislation. Indeed, several of the recommendations are standard operating procedure for those federal agencies involved in funding or regulating animal research projects.

For example, under current authority, USDA's Animal & Plant Health Inspection Service requires nearly all private and state-owned research facilities to register, and is required to inspect these facilities. Federal laboratories are required to meet the same standards. The Department of Health & Human Services will not grant awards to any institution that does not file with the department a statement of assurance committing the institution to a satisfactory program of animal care. Likewise, HHS requires these institutions to maintain animal care committees, and has begun a program of spot inspection.

In summary, AFMA contends S. 657 is premature since no verifiable record of animal abuse exists, and, in the final analysis, is unnecessary since the legislative recommendations included in S. 657 have been implemented in large part under the existing authority of the Animal Welfare Act.

APMA wishes to thank the Senate Agriculture Committee and Sen. Dole for the opportunity to comment on S. 657. We also wish to offer our assistance to any member of the committee or staff on the very vital issue of animal welfare.

STATEMENT OF LEON C. HIRSCH, PRESIDENT
UNITED STATES SURGICAL CORPORATION

United States Surgical Corporation ("U. S. Surgical") is the leading producer of surgical stapling devices used to close wounds and reconstruct tissue during surgical procedures. Surgical staplers are standard equipment in operating rooms throughout the world and U. S. Surgical is continuing to develop new products and to refine our current devices.

U. S. Surgical is a research facility under the provisions of the Animal Welfare Act (the "Act") and we are vitally interested in amendments to the Act which bear directly not only on the way we develop new surgical devices, but also on the subsequent patient safety and on how our highly-specialized technical salesforce trains surgeons and operating room personnel on complex surgical devices before the surgeons use these devices on human beings. Surgical devices must undergo the most rigorous testing procedures during development, including live tissue testing for chemical body reaction and hemostasis (control of bleeding). There is no method of testing for control of bleeding other than testing on live tissue. Our highly trained technical salesforce routinely assists medical teaching universities in the training of their residents and surgeons. This live tissue training with surgical stapling devices is performed either in our laboratories or, by invitation, in the laboratories of the teaching university. It affords surgeons essential training in the use of stapling devices prior to operating on human beings.

U. S. Surgical, as a facility that has the full accreditation and certification of the American Association for Accreditation of Laboratory Animal Care ("AAALAC"), operates under animal care standards that far exceed the current statutory and regulatory "minimum" requirements. U. S. Surgical readily endorses the underlying concept of S. 657 to insure the proper treatment of laboratory animals, and would urge other registered research facilities to assure humane treatment for laboratory animals. We believe that this objective is best obtained through legislation that rectifies problems or abuses where they actually exist. In this regard, we urge this Committee and the Congress to deliberate very carefully on S. 657 and other proposed legislation to protect laboratory animals in order to avoid any unintentional results which could hamper medical research, developing technology or essential training.

Our concerns with S. 657 are addressed to three general areas. First, it is our belief that the thrust of S. 657 is directed at the use of animals in research supported by federal funds and that private laboratories which receive no federal funding should be exempt from the proposed legislation. Second, we suggest there is an enormous distinction in the proprietary interests of government research and private industry and we are extremely concerned about the protection of trade secrets and other private proprietary rights under the provisions of S. 657. Whereas in federally funded laboratories, information should be shared to reduce duplication and unnecessary animal use and expense, private laboratories are entitled to exclusive rights to the fruits of their research and must assure complete confidentiality in order to protect their proprietary rights. Lastly, we urge careful evaluation of the true cost imposed on research facilities for good faith compliance with the requirements in S. 657.

As stated, we question whether S. 657 should apply at all to research facilities that do not receive any federal funds. Clearly, the thrust of S. 657 is to clarify the extent to which institutions receiving federal funds must insure the proper treatment of laboratory animals. For this reason, Section 2 of the bill amends the definition of "research facility" covered by the Act, and Section 4(g) of the bill specifies under what circumstances such federal support shall be suspended or revoked. We believe the Committee should determine whether there is any need to include private research facilities in the proposed legislation. U. S. Surgical is currently subject to the inspection of two federal and two state agencies in addition to the more stringent requirements for AAALAC certification. We question whether an additional inspection by an "institutional animal studies committee" is necessary, especially in light of the trade secrets-proprietary rights question.

One solution would be to have the "committee" provision apply to research facilities receiving federal funds. As a minimum, we suggest it is proper to exempt any private facility which is AAALAC certified for as long as such certification is in effect.

A second area of concern to us is a provision in Section 4(d) of S. 657 that would require at least one member of such a committee to be not affiliated with the research facility and be primarily responsible for representing the community concerns regarding the welfare of animal subjects (page 5, line 10-16). Particularly, with respect to research facilities that operate in the private sector, it is critical that certain business information be closely guarded, sometimes even from other members of the research facility. For example, last April U. S. Surgical announced the development and marketing of the world's first absorbable surgical staple representing a major surgical advance and an immense potential patient benefit. However, it was critical for competitive reasons that the mere existence of the project leading to this break-through be closely guarded. We are not convinced that bona fide trade secrets or confidential information of this kind would be adequately protected by the vague "assurances" from the unaffiliated committee member provided in the bill, particularly if there is no enforceable contract between the member and the research facility. This kind of confidential information is the life blood of high technology industries and cannot be compromised.

We believe that the concern over the trade secrets issue should be addressed by inserting additional language prior to reporting S. 657 out of committee. Federal officers and employees, such as APHIS inspectors and others, face strong penalties for disclosure. Following that model, some concerns would be allayed if S. 657 were amended to provide that: (1) the unaffiliated committee member were required to execute and file with the Secretary an affidavit stating that he or she would not disclose trade secrets or confidential information to any other person, and would furnish any additional written agreement of confidentiality required by the research facility; (2) any disclosure of trade secrets or confidential information in violation of the affidavit or non-disclosure agreement would be punishable as a misdemeanor under federal law; and (3) any disclosure of trade secrets or confidential information would provide the basis for a research facility aggrieved by the disclosure to file a civil action in federal district court for actual and consequential damages arising out of or relating to the disclosure, as well as litigation costs, including a reasonable attorney's fee. While the United States Government may on certain occasions wish to pursue criminal prosecutions for disclosures of information that might be detrimental to its interests, we also believe that in many cases it will be private research facilities that have the greatest incentive to seek a remedy for wrongful disclosure of trade secrets or confidential information.

We concur in Senator Dole's stated intent that S. 657 not impose additional costs on research facilities. This Committee has a positive duty to determine to the best of its ability the actual cost burden for "good faith" compliance with the requirements of S. 657 in its present form. Obviously, to the extent there are costs required to comply with S. 657, they will be passed on somewhere. Federally funded research facilities will ultimately pass those additional expenses through as an increased cost of research and they will be borne by the taxpayer. In private research facilities the cost can only be passed on to the consumer. The Committee has a duty to ascertain those costs, and we suggest only several for consideration here.

For example, Section 4(b) of S. 657 (page 4, line 1) would require the Secretary of Agriculture to promulgate standards for the provision of "adequate exercise" of animals. Assuming that this new "adequate exercise" standard imposes requirements beyond those currently required under applicable federal regulations, we believe it is appropriate for the Committee to determine the approximate cost of additional capital outlays to meet the new standard. If there is to be no additional outlays required, the report language should clarify that point to avoid confusion and unnecessary expense.

The issue of cost also arises with respect to the proposed "institutional animal study committee" that would be established pursuant to Section 4(d) of S. 657 (page 5, line 1 - page 8, line 11). If such a committee is to perform the full responsibilities stated in the bill, it seems to us that there would be considerable resulting cost to research facilities. For example, beyond additional overhead expenses (such as photocopying costs, etc.), the lost productive time of some of the research facility's most highly trained and capable individuals would be substantial. The cost necessary to perform the responsibilities delegated to such a committee under this provision should not be regarded lightly.

Moreover, S. 657 imposes a requirement that such a committee "shall provide annual sessions" for personnel involved with the animal care and treatment in research facilities, but the bill does not attempt to specify the contemplated length or content of such "annual sessions," and apparently does not take into consideration the amount of productive working time that would be lost by research facility personnel in preparation for and attendance at such sessions. We strongly believe that your Committee should recommend such a provision only after it is fully apprised of the estimated cost of providing those annual sessions and only after every effort has been made to avoid additional cost by providing federal assistance or participation. At a minimum, the Committee's report should clarify the nature and scope of effort for the "annual sessions" in order to promote and facilitate compliance by individual research facilities.

In summary, we share the Committee's concern for assuring proper treatment for laboratory animals. We believe our own facility far exceeds statutory and regulatory requirements and we invite the Committee and its staff to visit our laboratory in order to see first hand a private research facility covered by the Animal Welfare Act.

We are available to work with the Committee to develop legislation which addresses, in a fair and equitable manner, our concerns and also accomplishes the intent of S. 657 to assure proper treatment for laboratory animals.

STATEMENT OF DR. JOHN McARDLE, DIRECTOR, LABORATORY ANIMAL WELFARE, HUMANE SOCIETY OF THE UNITED STATES

MR. CHAIRMAN AND MEMBERS OF THIS COMMITTEE ON AGRICULTURE

I am Dr. John McArdle, Director of Laboratory Animal Welfare for The Humane Society of the United States (HSUS). In representing The HSUS, I also represent our constituency of 200,000. I was trained as a researcher and earned a Ph.d. in Anatomical Sciences at the University of Chicago. I have devoted ten years to the study of animals in research, from teaching biology and physiology to university students, to my current position of advocate for laboratory animals. I am the author of two books and several scientific papers on primate functional anatomy.

The reduction of pain and suffering endured by animals used in research in this country is a top priority for The HSUS, as is the promotion of research into the development of techniques that would ultimately eliminate the need for laboratory animals altogether. Thus, it is in the spirit of humane science that I offer my comments.

It is now well established that the physical and behavioral environment in which laboratory animals are bred, raised, transported and housed (before, during and after any research, testing or educational procedures) has a direct, often major, influence on the physiology, biochemistry and behavior of those animals. Essentially everything the animals experience has a real or potential impact on the validity of results from each research project. Under the present system of laws, regulations and agency 'guides,' researchers must assume that published data and grant proposals involve laboratory animals that received appropriate optimal care, and that the studies are not biased by poor experimental design, inadequate care and maintanence, abuse, neglect, pain or distress of the research animals. Furthermore, any attempt to compare experimental results between two or more institutions must assume equivalent, optimal care in each laboratory. The Humane Society of the United States (HSUS) believes the present system of regulations, inspections, assurances and peer review have failed in a significant number of cases to provide uniformly proper care of animals used in biomedical research (e.g. the cases of (1) Dr. Edward Taub and (2) the University of California-Berkeley). By allowing less than optimal care of laboratory animals, the existing system has the potential to invalidate or limit the usefulness of taxpayer-funded biomedical research, endangers the public health with faulty tests and experiments, and represents an unacceptable ethical cost resulting from potential neglect or abuse of research animals. We believe S. 657 will alleviate many of these concerns and encourage appropriate use of federal tax dollars supporting valid biomedical research.

The existing Animal Welfare Act and National Institutes of Health (NIH) Guide both stress minimally acceptable standards of care and maintenance. This is not sufficient to establish and maintain normal physiological or behavioral parameters. Appended to this testimony is a detailed review of this problem prepared by the Scientific Director of The HSUS, Dr. Michael Fox. We strongly endorse the change in emphasis from 'adequate' to 'proper' requirements. Furthermore, we vigorously urge that 'proper' be interpreted to mean species-specific needs and that 'behavioral needs' be added to the list of variables covered by the improved standards. There is no justification for the common practice of placing a heterogeneous population of animal species into a homogeneous laboratory environment. In their natural habitats, these animals have well-defined, species-specific characteristics. These are not lost when the species are domesticated or confined to the research laboratories. Most institutions presumably already have the presently required minimal standards. If they do not, then the research conducted in their laboratories has questionable validity.

As is obvious from human clinical experience and modern veterinary practice, lack of exercise or activity produces a variety of physical and behavioral pathologies, and retards healing in response to accidentally or experimentally induced injuries. We strongly endorse the long-overdue recognition that research animals need physical exercise in order to maintain normal baseline physiology and behavior. One method to facilitate this new requirement is to allow research animals the opportunity to engage in their natural behavioral repetoires. (See testimony of Dr. Fox for further discussion.)

Although the value of proper post-surgical and nursing care is a basic tenent of modern veterinary practice, it is not universally characteristic of biomedical research laboratories and is often absent in testing laboratories, whose goals may be to allow the animals to die as a consequence of the testing protocols. As a graduate student in anatomical sciences, I was routinely told that post-operative nursing care and use of analgesics for my experimental animals (which were involved in surgical procedures) was not a serious concern. Revelation of the problems in the laboratory of Dr. Edward Taub, Institute for Behavioral Research, unequivocally established that the existing laws, regulations, inspections, NIH assurances and NIH peer review procedures are unable to identify or prevent the grossly inadequate conditions and lack of proper veterinary and nursing care at that institution. S. 657 requires the formal recognition of these needs and provides the means to ensure their implementation. Since such procedures will improve both the quality and reliability of taxpayer-supported biomedical research, we do not understand the rationale for opposing their implementation.

The HSUS continues to be amazed at the extent to which representatives of the biomedical research community consistently misrepresent the content and intent of S. 657. This legislation clearly differentiates between interference in the intellectual freedom of inquiry of the individual researchers (a theoretical function of the existing peer review system), and oversight and review of the treatment and care of animals used in biomedical research. Few scientists have sufficient experience or knowledge in such areas as veterinary medicine, anesthesiology, and ethology to adequately provide for and moniter the care of their laboratory animals. This is a valid area of concern for the Secretary, APHIS, and the veterinarians employed to inspect for compliance with the proper standards included in S. 657. This proposed legislation specifically states:

> Nothing in this Act shall be construed as authorizing the Secretary to promulgate rules, regulations or orders with regard to design of research or experimentation by a research facility.

Scientists are still free to propose any research protocol. S. 657 will only act to ensure that proper maintenance and care of laboratory animals are included. This is a prerequisite for any valid research project and should be supported by the scientific community.

It is often stated that NIH suggestions in their "Guide for the Care and Use of Laboratory Animals," peer review, and annual reports of compliance by grantee institutions are sufficient to ensure proper care and treatment of laboratory animals. However, NIH only interacts with approximately half of the laboratories registered to perform animal experimentation. For this reason, the minimally acceptable standards of NIH are not universally applied in the United States research community. In addition, those labs receiving funding from NIH are not subject to routine inspections to verify their written assurances. As an initial attempt to reduce biasing factors in biomedical research, we strongly believe that the proper standards included in S. 657 need to be applied to all institutions using laboratory animals in basic research, product testing and education.

The single, most significant portion of S. 657, that which distinguishes it from the presently inadequate system and which assures compliance and uniformity of proper laboratory animal care, is the requirement for an Animal Studies Committee (ASC) (presently only characteristic of institutions receiving NIH funding), and the structure and duties of that committee. There are several key features of the proposed ASC which we very strongly endorse. These include:

1. At least one member is not affiliated with and thus not

biased or obligated to the research facility. The only possible mechanism to ensure compliance with the newly required proper standards of care, and that the public's legitimate concerns about laboratory animal welfare are considered, is to have such an individual, responsible for representing the local communities' interests. Since the public pays for this research and testing with their consumer and tax dollars, and supposedly benefits from those uses of laboratory animals, we believe it is time to open the research establishments to the refreshing light of public accountability.

2. The committee should meet regularly and not on a schedule dictated by a single individual (i.e. the chairperson). If a serious problem arises, any member of the committee should be able to schedule a meeting.
3. At a minimum, the committee should inspect all areas of the institution involved in the use of laboratory animals semi-annually. These inspections must be unannounced and include the individual research laboratories. The former is necessary to avoid simple ritual visits of temporarily sanitized and proper facilities. The latter would prevent the increasingly common practice of individual researchers secretly maintaining animals in their laboratories in order to avoid paying per diem charges to a central animal facility. Unless identified, these animals have no protection under existing laws and regulations, regardless of the species involved. We would further urge that the Secretary authorize inspectors to examine individual research laboratories rather than myopically restricting their activities to central animal rooms and facilities.
4. The committee should review research methods, protocols and practices to ascertain if investigators are

properly addressing such issues as humane care, behavioral needs, veterinary practices, anesthesia and analgesia. As clearly stated in S. 657, this is not done to intrude on the individual scientist's freedom of inquiry or scientific decisions, but to "ensure that animal pain and distress are minimized and to ensure compliance with the standards for appropriate animal care, treatment, and methodology."

5. The provision to allow for filing of minority opinions is important and must be maintained. This is the only mechanism to ensure that serious violations will not be covered-up by a majority vote of the committee. Further, we strongly believe that the committee reports must be available for inspection by the public, to ensure compliance and that the outside member is actually reflecting the interests of the local community.

The University of Southern California (USC) presently has a committee with a structure and role similar to that proposed in S. 657. The existence of this committee has neither slowed nor impeded the biomedical research activities at USC, but has introduced the concept of ethical responsibilities to their biomedical research community.

On August 3, 1983 Professor K.J. Obrink from the Uppsala Biomedical Center addressed the International Council for Laboratory Animal Science on the Swedish system for compulsory ethical examination of animal experiments. His abstract notes that:

> Since 1979 it is compulsory for Swedish scientists to let a local ethical committee examine animal research projects before start. The initiative was taken by scientists in Uppsala, in 1976 with a pilot experiment that included Uppsala University, the Swedish University of Agricultural Sciences, several state institutions and one pharmaceutical industry.
>
> The committee was and is composed of scientists, technicians and laymen. The idea was that the committee should advise the applicant and be his or her extended conscience. A project can be started after approval of a small group of three members of the committee. The committee itself is very large so that members should be

> available at all places where animal experiments are performed. It was hoped that bureaucracy in this way could be avoided.
>
> The experience as a whole is good. It has improved the communication between laboratory and society. The scientists express a positive attitude.

We fail to understand why the United States biomedical research community so adamantly seeks to maintain the existing closed-door attitudes with regard to public knowledge and participation in local research activities. Where such public input has been tried, it has been successful.

The requirement that the committee establish annual sessions for training in humane methods of animal maintenance and experimentation, concepts of alternatives to traditional methods of research, and utilization of the newly established information service at the National Agricultural Library is excellent and will counter the general level of ignorance on these subjects. We believe attendance at these sessions should be mandatory for all scientific staff and graduate students. Animal care technicians and other general staff should attend the sessions on humane care. Research faculty often automatically resort to the traditional animal model approach to answering biomedical questions. Efforts to minimize the numbers of animals used, the degree of pain or suffering, and to seriously assess the available alternatives, should be part of all graduate student training and research faculty attitudes. A formal, mandatory series of courses could remedy this situation. Longevity of a researcher or a research program does not automatically correlate with substantial knowledge of the proper needs of the laboratory animals or to advances in relevant alternative techniques.

There is no evidence that establishment of an ASC would entail significant new costs to research facilities or their host institutions. Membership on such ASCs can be considered part of a faculty member's normal committee responsibilities, which are generally done gratis. The requirement for a new series of courses could be included in the normal teaching load of the respective faculty members in the ASC.

We strongly endorse the provision protecting the employment of any individual who reports violations at their respective institutions. We routinely receive information on problems at individual research laboratories. Without exception, these individuals request anonymity because they fear losing their positions. Further, we have documented instances where individuals who raised these issues were fired.

The establishment of an information service at the National Agricultural Library should improve the quality and reliability of biomedical research in the United States by providing information on alternatives that reduce or replace animals traditionally utilized in research, refinement of existing techniques and procedures to minimize pain and suffering and focus on the increasingly serious problem of research funds and animals wasted in "unnecessary duplication of animal experimentation." Although replication is a fundamental principle of experimental science, interminable repetition is not.

We believe such a center would accomplish several positive goals, including:

1. Conservation of research money by careful examination of the relevant issues in the planning of research proposals. By always attempting to utilize methods that minimize the numbers of animals required, the cost of individual projects could be reduced.
2. Many of the presently available alternative techniques are more reliable and more time and cost effective than the traditional methods. Animal tests for carcinogens can take three and a half years and half a million dollars to complete. Use of comprehensive non-animal alternatives would provide identifical protection and take only three months at a cost of only $25,000. This is an example of the power of the alternative techniques. When properly developed and applied, such methods provide the needed information, while more

efficiently utilizing the available research funds.

3. Provide a mechanism to avoid funding unnecessary duplication of experiments, thus freeing money for valid, new studies that may provide new information, rather than encourage further insignificant parametric tinkering in fundamentally similar projects.

Although the biomedical research community claims that the existing peer review system addresses all of the issues raised in S. 657, there is well-documented evidence that this is not correct. Included with this testimony is a detailed "Evaluation of Awarded Grant Applications Involving Animal Experimentation" which examined funded biomedical research projects to determine if scientists receiving federal funding for their research considered humane perspectives in their applications. Using the National Institute of Mental Health as an example, they found that only 62 percent of the grantees considered the appropriateness of the animal models selected for their projects, 41 percent discussed the applicability of alternatives to vivisection, 57 percent considered the efficiency of animal use (i.e. selection of the appropriate species and methods to minimize numbers used), and less than 45 percent described the adequacy of their research facilities to maintain laboratory animals and to minimize the stress to which they were exposed. Even if grantees were honest and thorough, the information needed by the peer review panels was not generally present.

There are five distinct points at which the peer review system could significantly affect the treatment and use of laboratory animals. The process of preparing, submitting and reviewing grant proposals is the most obvious point of influence. Additional pressure could result from: (1) direct observations of laboratories and animal facilities by research colleagues; (2) the selection and discussion of papers presented at professional meetings; (3) evaluation of papers submitted for publication in scientific journals; and (4) consideration of promoting research faculty to tenured positions.

Despite the many opportunities for the peer review system to address the concerns discussed in S. 657, it is not being done. However, the peer review process will become more effective as a result of the certification required on page 9, section (f) (1), that the appropriate aspects of individual experiments concerning care and treatment of animals must be addressed. In particular, we strongly support the requirement that every research proposal to a federal agency contain:

1. detailed justification for "any procedure likely to produce pain or distress" and evidence that all possible alternatives to that procedure were considered. This should include a detailed explanation for the rejection of any of these alternatives.
   Although there may be technical disagreements on how to measure pain, its presence is easily recognized and can be scaled with respect to relative intensity.
2. evidence that a qualified veterinarian participated in the planning of the project.
3. assurances that proper anesthetics, analgesics, tranquilizers, and post-operative medical and nursing care.
4. assurances against unnecessary survival surgery.

We strongly endorse the mandated use of analgesics and requirements for post-operative medical and nursing care. These aspects of proper laboratory animal care are routinely ignored in many research laboratories. However, we are concerned by section (C) (iii), page 10. We recommend it be reworded as follows: "(iii) against use of paralytics without surgical levels of anesthesia confirmed by central nervous system monitoring; and"

The use of paralytics without full, surgical levels of anethesia must be banned. Further, the Act should require that central nervous system activity be monitored throughout any procedure combing paralytics and anesthetics. This is the only acceptable method to avoid the situation where an animal regains consciousness, but is still paralyzed and thus experiencing intense pain from the surgical procedures.

In its present form, The Humane Society of the United States support S. 657. We note only one major deficiency. As with the present Animal Welfare Act regulations, the provisions of S. 657 do not require the Secretary to extend protection to all warm-blooded animals used in research. Currently, the Secretary chooses by regulation to specifically exclude rats, mice, and birds. At the present time, 76 of the 80 million laboratory animals killed annually in United States research and testing facilities are excluded from any legal protection. We will accomplish little if S. 657 does not include these voiceless and unprotected animals within its provisions.

STATEMENT OF CHRISTINE STEVENS, SECRETARY, SOCIETY FOR ANIMAL PROTECTIVE LEGISLATION

The Society for Animal Protective Legislation strongly supports S.657, a carefully drafted bill which has been subjected during the course of its development, to thorough scrutiny, by both animal welfare and scientific groups. A concerted effort has been made to present to the Senate legislation which comes as close to consensus as a bill in this field, historically noted for unresolved controversy, can be expected to come. A few years ago such agreement among major scientific and humane organizations would have been impossible.

Now this distinguished committee has an unusual opportunity 1) to lessen pain and distress for the millions of animals that give their lives to improve human health, 2) to improve research and testing in our country, and 3) to take a practical step toward reducing government expenditures wherever it is scientifically feasible to cut down on the use of laboratory animals.

A New Consensus on Reducing Numbers of Test Animals

Remarkable progress has recently been set in motion in the development and use of alternatives, and in recognizing that some time-honored tests on animals are becoming obsolete in the light of new knowledge. The Pharmaceutical Manufacturers Association and the National Society for Medical Research have issued statements this year that "the routine use of the quantitative LD_{50} test is not now scientifically justified." This test requires that 50% of the test animals die from the effects of the test substance. Long criticized as an extremely cruel test, it nevertheless is still required by some regulatory agencies.

The Summer 83 bulletin of the Johns Hopkins Center for Alternatives to Animal Testing begins with these words: "It soon should be possible to reduce greatly the number of animals used in tests conducted by industry to satisfy government regulations on toxic substances." The center's director, Dr. Alan M. Goldberg, noted, "This is the first time that government, industry, and the concerned public have come together to produce such a broad consensus." The bulletin is attached.

The Importance of Animal Studies Committees

The Animal Research Position paper of the American College of Physicians 12 January, 1983 notes in part, "Where animal experimentation and testing are necessary, humane care and treatment that limit pain and distress should be assured. This may require the establishment of procedures not unlike human subjects protection review....The College recognizes the importance of standards that promote the conduct of quality research and ensure the humane care of healthy animals for research activities."

S.657 contains these principles. An important provision requires animal studies committees in each research facility to include a veterinarian and a member, not affiliated with the institution, primarily responsible for representing community concerns regarding the welfare of the animal subjects. The institution appoints the outside member, who must be a volunteer. There is no cost to institution or government for this valuable addition to ensuring proper treatment of laboratory animals.

Though S.657's committee structure is much simpler than the committees that have been established some years for human subjects protection review, the idea is similar and its soundness is attested by experience. Attached is a page from the Code of Federal Regulations, revised January 26, 1981 from which some of the language of S.657 was derived, in particular, "the IRB (Institutional Review Board) shall include one or more individuals who are primarily concerned with the welfare of these subjects...at least one member who is not otherwise affiliated with the institution."

Here, as elsewhere, S.657 steers a conservative course, relying on previous experience. The National Institutes of Health require grantees to have an animal care committee, and members of similar committees sign the annual reports required by the U.S. Department of Agriculture's Veterinary Services which administers the federal Animal Welfare Act. As an amendment to this Act, S.657 improves on existing law making use of already familiar systems within the institutions.

A major difference between the human subjects institutional review boards and the animal studies committees required by S.657 is the fact that the former have much more extensive authority. S.657 specifically exempts the design of experiments or tests from the authority of the Secretary to make regulations. The Animal Studies Committee is directed to make semiannual inspections and to review the research methods and practices to ensure compliance with the standards.

The Committee reports any unacceptable conditions it finds to the institution which is given an opportunity to make such conditions acceptable. If it fails to do so, the Committee notifies USDA's Animal and Plant Health Inspection Service and the granting agency, if any.

Opponents of S.657 have questioned the need for the Committee and its work. To show how urgent this need is, I append some reports of USDA inspections of major medical schools and other scientific instituions obtained under the Freedom of Information Act, and quote a few here. "Psychology Department, University of California at Berkeley: 'Primate cages are in a state of disrepair including broken, protruding wires...food being placed on bottom pans where it is contaminated by urine and feces....'

'Approximately 6 cricetid rodents left in pans on outside deck were drowned and left decomposing in pans....'

'Open bag of feed pellets still on table top, festooned with cobwebs.'"

"School of Public Health, UCB: 'No species separation - no cage washing - no quarantine space - poor ventilation control;' 'the room is filthy and infested with flies;' ' all food receptacles must be kept clean and sanitized at least every two weeks not just when the rabbits are changed (upwards of several months)'"

"Department of Zoology, UCB: 'Hot water has been inoperative for some time;' 'heavy fecal buildup...heavy fly and odor buildup.'"

"Division of Animal Resources, UCB: 'Random check of identification on cats - one cat had two tags - one with a USDA number (62095) and also a UC tag of 528 - 528 does not correspond to this cat.'"

"Stanford University Medical Center: 'pits in the floor an inch deep.' 'other rooms have no source of heat;' 'drain pipe of the sink in the necropsy room empties onto the floor.'"

'No ventilation (cats);' 'primate in a cage 13 by 25 inches that does not provide adequate space for this animal;' 'algae in the watering bottles.'

'Rabbits are being splashed with wash water and/or acid during cleaning. Observed rabbits with sore hocks and soaked matted hair masses.'

'Whelping room...no ventilation;'

'Frozen and broken water bottles.'"

Despite these reports, with which the institutions are familiar, there have been years of foot dragging. Clearly, institutional committees require the back-up which S.657 would give them to correct these sordid conditions which make life hideous for the animals and exert a harmful influence on the research which uses them. USDA's veterinary inspectors deserve praise for their efforts to correct mistreatment of these animals. They, too, need the provisions of S.657 to be effective in the work Congress assigned to them when the Act was passed in 1966 and amended in 1970 and 1976.

Major Operative Procedures

Another provision of the bill based on an already established concept is the assurance that no animal may be used in more than one major operative procedure from which it is allowed to recover except for scientific necessity or unless the animal studies committee has determined that another special circumstance warrants it. The last two revisions of the NIH *Guide for the Care and Use of Laboratory Animals* have contained a similar statement, devised by scientists who observed severe suffering of dogs used in repeated practice surgery operations by medical or veterinary students. Thirty years ago, it was common to use a dog for five or even seven major operations for no better reason than to save the five or ten dollars dogs cost in those days. I have seen these pathetic creatures cringing in their cages, and I remember the remark of a doctor who took me on the tour of the animal rooms boasting about the dogs' treatment which he considered so wonderful that he said they were "spoiled."

Attitudes like this are at the root of indifference to animal pain and distress. There is a form of blindness, which I have often observed in the course of decades of visiting laboratories, that makes legislation exemplified in S.657 so necessary. It is easy to become accustomed to the sight of needless suffering and even easier when, as is often the case, responsible individuals in an institution rarely even look at the animals,

Assurances on the Prevention of Unnecessary Pain

The other assurances, required by S.657 before a Federal agency may approve a grant, are all simple, logical requirments which most people probably assume would be routine in all laboratories - indeed they are in well run institutions. But when we read about "the swamp" in Industrial Biotest Laboratories (headed by a professor in Northwestern University Medical School) where the test animals died of starvation and thirst for want of minimal attention to their needs, and realize that it has taken ten years, plus major charges of fraud, for the government to catch up with the situation, it is clear that specific assurances for commercial laboratories are essential. According to The New York Times, Industrial Biotest was "one of the nation's largest research laboratories." The article is attached.

To sum up the further assurances, they require the principal investigator to consider possible alternative methods to any procedure likely to cause pain or distress and to consult a doctor of veterinary medicine in the planning of any such procedures; to make proper use of tranquilizers, analgesics and anesthetics; to provide appropriate pre- and post surgical medical and nursing care; to provide adequate anesthesia if paralytics are used, and, finally, to withhold pain killers or euthanasia no longer than is scientifically necessary. This last is of great importance in reducing needless and useless agony. To avoid the bother of killing moribund animals, they are often left to die slowly and painfully.

As noted earlier, indifference coupled with failure to look closely at the animal subjects is a major cause of animal suffering in laboratories. As recently as July fifth, Ohio State University agreed to pay a $500 civil penalty for having allowed 40 kittens to suffer horribly from a particularly virulent form of neglect. To quote the laconic USDA report, "The kittens had lesions around their necks, and many had metal chains with identification tags imbedded in the flesh of their necks. These injuries apparently resulted from chains being placed around the kittens' necks when they were young and not being replaced or lengthened as they grew older."

Had an animal studies committee including a member responsible for community concerns for the welfare of the animals made conscientious semi-annual inspections, such an occurrence could never have taken place.

Exercise Requirement

The standards for care and housing of animals remain the same as under existing law in the proposed amendment except for changing the words "minimum standards" to "proper standards" and the addition of provision for adequate exercise under S.657. There has been a general move from perpetual caging of dogs to the use of floor pens which are far more healthy and comfortable for the animals and easier for their handlers, who do not have to lift dogs down from double tiered cages. (They were often triple-tiered before passage of the Animal Welfare Act). However, to bring the remaining institutions up to what is now the norm. this requirement is needed.

No Discrimination Against Those Who Report Violations

An important part of S.657 which has proved its worth in other analgous circumstances is the provision protecting employees from discrimination for reporting violations of the law which they may observe. The bill directs institutions to inform staff to report any violation to the animal studies committee.

It has been found that provision of immunity is an essential prerequisite in obtaining reports on battered children so they can be protected. In the commentary on the Model Child Protection Act we even learn that penalties for failure to report are needed: "...nurses frequently relate how the mention of the potential penalty for failure to report is the only argument that convinces hospital administrators to commence protective action."

The modest protection from discrimination contained in S.657 is an essential provision which must not be lost. As a deterrent to violations it is peerless, for anyone tempted to violate the law will have at the back of his mind the fact that he no longer can silence other staff members by fear for their jobs if they report mistreatment or neglect of animals.

Although the staffer reports only to the committee, not to the USDA inspector, the existence of this provision will aid him because it will reduce violations for which he must be on the lookout. It is the most inexpensive form of constant supervision that can be devised, and it is sorely needed, for fear of retribution silences many, from scientists to technicians, and thus abuses flourish uncurbed when they could be easily prevented.

Educational Provisions

The bill's educational features, while modest in cost, can be highly effective. Central to this aspect is the establishment of an information service at the National Agricultural Library which, in cooperation with the National Library of Medicine, will provide information on methods that reduce or replace animal use, minimize pain and distress and prevent unintended duplication of animal experiments. The animal studies committee is instructed to make use of this service in providing annual sessions in humane practices for scientists, animal technicians and others.

Farm Animals Are Exempt

As an amendment to the Animal Welfare Act, S.657 is administered by the Secretary of Agriculture. Agricultural interests should be especially pleased by this fact, and indeed the majority are. Regrettably, others, though totally exempt from the bill's requirements. nevertheless oppose its enactment. They do a distinct disservice to the farmers who are their constituency by opposing a much needed humane bill which farmers as individuals would take no interest in opposing.

Curiously, these groups support the study bill which has been incorporated in the NIH authorization bill, yet I was told by one of the staffers who worked on it that he particularly wanted to see a study of the treatment of farm animals.

S.657, in constrast, specifically exempts farm animals because it amends the Animal Welfare Act which excludes from the definition of the term "animal" "horses not used for research purposes and other farm animals, such as, but not limited to, livestock or poultry, used or intended for use as food or fiber, or livestock or poultry used or intended for improving animal nutrition, breeding, management or production efficiency, or for improving the quality of food or fiber."

This exemption has been in place for years and though this is the third time amendments to the Act have been proposed (amendments were passed in 1970 and 1976) no change has ever been proposed to the exemption. The Act focuses on biomedical research and testing laboratories, their animal suppliers, and the transportation of these animals and other dogs, cats and wildlife exhibited in zoos and circuses.

Study Bill Supported as a Delaying Tactic

The Association for Biomedical Research, which favors the study bill rather than S.657, made a frank statement about their reason for supporting last year's study bill. "This approach," ABR's Update said, "would, more than likely, spin off the animal research legislation for several years."

ABR is a trade association founded by the world's biggest laboratory animal breeder and dealer, Charles River, an unabashed promoter of sales of the maximum number of any and all of its species. Not surprisingly, a bill that asks scientists to consider alternatives to animals in experiments and tests has not found favor with the multimillion dollar multinational firm or the association it spawned.

Charles River Breeding Laboratories in Wilmington, Massachusetts had seven NIH research and development contracts for 1982 totalling $4,520,824.

Animal Dealer's Negligence Contibutes to High Cost of Research

This was also the year in which the company dispatched over a period of 15 months, more than 100,000 mice of a supposedly genetically pure strain to scientists throughout the country who later found their experiments ruined because the mice were not as advertised. Described as "a catastrophe" in Science the matter was shrugged off by Charles River. According to The New York Times, "the company which breeds some 22 million animals of all kinds a year, estimates that it shipped only about 28,000 of the suspect BALB/c mice to cancer researchers, the field of most concern." More than a thousand experiments were estimated to have been affected, giving the scientific community a complicated mass of erroneous research data to try to clean out of the system.

Charles River is well known for its full-page ads featuring puns (see attached "A Cynonym for Quality" featuring a cynomolgous monkey). "So next time you're faced with a problem of availability, don't put your research on hold," runs the ad copy. "Link up with a primate that means quality. Our cyno. Or any of our other 10 commonly used species." Who could guess that habitat destruction and the laboratory primate trade has pushed so many species to the brink of extinction that all primates have been placed on Appendix I (endangered) or Appendix II (threatened) of the Convention on International Trade in Endangered Species of Wild Fauna and Flora? Primates have become more and more precious to researchers as their numbers have dwindled. It is vitally important that they not be subjected to casual mishandling, yet under the existing Animal Welfare Act Charles River Research Primates (formerly Primate Imports) paid a $3,500 fine in December 82 for a series of violations in shipping monkeys. The cramped cages, too fragile and damaged to be safe either for the human handlers or the animals lacked handholds, wild animal identification and feeding instructions.

Alternatives

Once arrived in a scientific institution, primates may be subjected to further unnecessary distress. A valuable alternative to the widely advertised monkey chairs formerly used at Fort Detrick is a vest and tethering system. To quote from the journal Laboratory Animal Science, (Vol. 30:4:706-708) "Chair restraint of 3-5 Kg nonhuman primates...for up to 14 days during infectious disease studies led to restraint related complications including ischial pad sloughing and decubital ulcers." Decubital ulcers (bed sores) are painful and difficult to cure once established. Some monkeys fight the chairs so intensely that severe injury sometimes leading to death results. Thus the vest and tethering system, which has enabled Fort Detrick to discard all its monkey chairs, represents an important humane alternative which incidentally saves money for the Government. I have personally observed this valuable change in primate handling at Fort Detrick.

Even though it substituted for monkey chairs in one major primate laboratory, the vest is not a substitute for every use of the monkey chair, but it is an important example of one of the forms of alternatives described by the "3 R's": Replacement, Reduction and Refinement first described in the book Humane Experimental Technique by Russell and Burch (1959). The vest is an example of refinement as contrasted with the rigid and injurious restraint of the chair (see photos).

Examples of replacement include the many vaccines now manufactured from tissue cultures which replace conscious animals formerly forced to undergo the disease. Another well known example is the replacement of rabbits, then African frogs, for pregnancy tests which are now performed without any animals at all.

Examples of reduction include the current lessening of numbers of animals used in the LD_{50} test referred to earlier. Results of a symposium on the LD_{50} published in Acta Pharmacologica et Toxicologica (Vol 50, Supp II, 1983) indicate that other toxicological tests can also be reduced with respect to total animals.

Cultures of human cells or organs give specific results for tests of substances to which animals may react differently. On Walter Cronkite's "Universe" last August Dr. Marvin Pollard former President of the American Cancer Society stated: "My own belief is that we have relied too heavily upon animal testing, and we believed it too strongly. Now, I think we're commencing to realize that what goes on in an animal may not necessarily be applicable to a human being."

An excellent reference book giving existing alternatives coupled with current animal experiments is Alternatives to Pain in Experiments on Animals, by Dallas Pratt, M.D. (1981). Copies have been made available for the Committee's use.

Pain and Distress

A second reference book, Physical and Mental Suffering of Experimental Animals, gives examples from a variety of scientific disciplines of experiments which cause serious pain and distress. The categories indicate the contents (Eye Manipulations, Burn Experiments, Noble-Collip Drum Trauma, Radiation Research, Brain Research, Electric Shock Research, Aggression Research, Stress Experiments and Miscellaneous Manipulations). Copies of this book have also been made available.

The measurability of pain and distress has been raised as an issue in connection with S.657. But there is no issue here. The bill aims to minimize pain and distress. It does not seek to measure it. If two people in a dentist's office are suffering from a tooth ache, there is no need to attempt to determine whose pain is the most intense. The dentist will seek to alleviate the pain in both cases. He will do this by giving pain relieving drugs and/or treating the cause of the pain. The same principle obtains in S.657. That is why a veterinarian is required to consult in the planning of "direct use of conscious animals" where pain may result. He can help avoid unnecessary pain or recommend treatment to minimize it.

Summary

S.657 is designed to minimize laboratory animal pain and distress. It amends the Federal Animal Welfare Act for the third time. It has been drafted in close consultation with major scientific and humane groups. Farm animals are exempted. No major costs for either the research facilities or the Federal Government are involved in the implementation of S.657. It should be passed promptly.

WARDS,
Washington, D.C., July 18, 1983.

Hon. ROBERT DOLE,
U.S. Senate,
Washington, D.C.

DEAR SENATOR DOLE: We are so grateful you and other committee members are taking an interest in the care of animals in research. After all, much of our present research depends for accuracy on a uniform high quality of animal.

Although Wards applauds the objective of improving standards for laboratory animals, we believe the performance record of the Department of Agriculture in enforcement precludes any extension of authority to that agency. We thought in 1966, when the Animal Welfare Act originated, that USDA was the logical enforcement agency; however, it has been a dismal failure in this unique situation. Agriculture is not positioned to make a success of this responsibility. It would have to have the wisdom of Solomon and the clout of a tycoon to manage this successfully. Split authority between Government agencies always results in no authority. We believe that the Department of Health and Human Services, the main source of research funding, should be given responsibility for animal care. The buck should stop where the buck originates. Protective measures are easily enforced when funds are at stake. DHHS should take responsibility for the condition of animals whose use is financed by funds under its jurisdiction.

At the time of the *Taub* case in Maryland, we presented to the Walgren Committee of the House, the enclosed larger explanation of our ideas and clipping relating to that case. Subsequently, the USDA inspector was used as a *Taub* defense witness. We hope these will be placed in the hearing record and made a part of your deliberations.

Again, thank you for your kind concern. The present disorder for animals should not continue.

Sincerely,

PEYTON HAWES DUNN, *Chairperson.*

[Reprint from the Washington Post, Saturday, Sept. 12, 1981]

POLICE RAID LAB, SEIZE ANIMALS

(By Ronald D. White)

Montgomery County police yesterday raided a medical research center in Silver Spring and seized documents, samples and 17 monkeys that they said may have been mistreated in ways that violate the Maryland State Animal Cruelty Law.

When police, acting on the basis of a search and seizure warrant, entered the Institute for Behavioral Research, they said they found "monkeys who were in such physical and mental stress that they appeared to have bitten off their fingers and arms, or whose cages were locked together so that they injured each other."

The raid resulted from information supplied by Alex Pacheco, a 23-year-old George Washington University student who had worked at the center for the last four months as a volunteer. Pacheco said he went to police earlier this week because he was appalled at the condition of the animals he saw.

"I saw one animal totally collapse from not being fed . . ." he said. "I was told to torment and frustrate [the monkeys] and watch their reactions."

According to Dr. Edward Taub, principal investigator at the Institute for Behavioral Research, the monkeys were used in invaluable experiments on the effects of damage to the central nervous system. The institue had received $60,000 from the National Institutes of Health for the study.

"We were concerned with neural regeneration and regrowth," Taub said, adding that the research had already resulted in important gains in learning how to enable humans to recover from strokes. "I'm surprised, distressed and shocked by this. There is no pain in these experiments. We surgically abolish pain."

But Dr. Geza Teleki, an international expert on primates and an associate professor at George Washington University who viewed conditions at the facility before the raid, disagreed. "There's no way to walk into that [facility] without feeling that you're in some kind of hell," Teleki said, adding that the raid was the first of its type on a biomedical research facility in the country.

No one employed at the research center has been charged, but police spokeswoman Nancy Moses said that experts would be brought in to examine the animals along with samples of food and feces that were also collected.

The penalty for animal cruelty is a $1,000 fine and/or 90 days in jail. "After examining financial and medical records seized, police will determine if any federal laws have been violated," Moses said.

The institute's chief executive, Joseph Vasapoli, said that IBR had just passed "an inspection from the state. Everything was fine. I have documents to prove that it was right. We had appropriate clearances. We take very good care of our animals. We've been doing research with these monkeys for eight years or more."

Specifically, according to Taub, that research involved a process called "deafferentation"—where the spinal reflexes of crab-eating macaque monkeys are "abolished" by surgery. The central nervous systems of the monkeys are then tested to determine their recovery from the damage, Taub said. He said that the research has resulted in invaluable insights in improving the recovery of stroke victims.

"What the research has told us is that a certain percentage of stroke victims learn not to use the damaged limb," Dr. Taub said.

The experiments involve strapping a monkey's good limb in a way that forced it to use the limb that had no feeling, Taub said. He added that the process was similar to "lazy eye" treatment in which the good eye is covered, forcing a person to use the weak eye, which is strengthened through use.

Taub said that such a process means that "the monkey frequently cannot help damaging himself because there is no sensation in that limb. . . . We have set procedures we carry out routinely and they have been approved by the Department of Agriculture."

Laboratories at the institute's two-story building in an industrial park near the Walter Reed Hospital annex were inspected twice this year by the Agriculture Department's animal and plant health inspection service, according to Dr. I. H. Huff, the official charged with Maryland. Huff said yesterday that he had "just chewed out the inspector for 45 minutes" after hearing about the police raid.

According to Huff, the institute was cited in an April 1981 inspection for deficiencies in "interior surfaces, sanitation and cleaning," but that an inspector subsequently ruled in July that those deficiencies had been corrected and "no [new] deficiencies recorded."

"I think that the animals surely suffer under this type of research," Huff said. "But this has been judged a worthy study by NIH. If it is determined that suffering is a necessary condition of the test, then we can't interfere."

STATEMENT
BY
WARDS INC.
2225 Observatory Place, N.W.
Washington, D.C. 20007

For the

SUBCOMMITTEE OF SCIENCE AND TECHNOLOGY

of the

HOUSE COMMITTEE ON SCIENCE AND TECHNOLOGY

USE OF ALTERNATIVES AND PROFESSIONAL CARE OF ANIMALS IN RESEARCH

WARDS has been interested in the care of animals in research since 1954. We are grateful for the opportunity to submit our statement. We have known for years that there is no practical protection for animals in research despite the Animal Welfare Act of 1966. Even human subjects are just beginning to find protection. This was made clear at a House hearing of the Subcommittee on Research Oversight when Congressman Gore and others tried to discover any orderly procedure for action at the National Institute of Health (NIH) when abuse, such as injecting humans with DNA, was evident.

WARDS understands the research community's efforts to protect the freedom of the scientific processes. As Dr. Donald Frederickson, Director of NIH, said at this hearing,

> "The general community is generally willing to concede that agencies dispensing the funds have the right to exact certain requirements in their expenditures and accounting. Where the substance of science is involved, however, a more strongly held bias against administrative intervention comes into play."

In his insistence on protecting the scientist from the "too quick or strong invasion" by even their own peer group, however, it became clear that one of the main purposes of NIH is to prevent interference with research by laws and inspectors ignorant of the purposes and procedures of research.

This protection is understandable but the spectacle of animals tucked away in unfit, poorly supervised, shameful factory-type housing across the country is where WARDS knows changes must come, and where the scientific community has failed completely to recognize the unnecessary stress and suffering that it inflicts. In the modern mass attack on disease and with the advent of new surgical processes, a new commitment is necessary to bring the care of laboratory animals up to a standard which will meet the animals' physical needs and reduce the variables which presently flaw scientific inquiry.

While protecting the integrity of science, WARDS believes that this integrity depends on the professional handling of the animals upon which science is based. To this end WARDS proposes a central NIH-based animal care center which would work directly with local research laboratories to provide information and practical help in standardized care of experimental animals.

The understanding of animal care should be taught to medical students when their first patient (the animal) is placed in their hands. Irresponsible indifference at this point can't make better doctors. In short, responsibility for animal care can't be printed and hung on the walls and forgotten. There should be sensible precautions from which scientists and students exercise professional freedom instead of unprofessional disorderly guesswork.

For the human patient, the running of the hospital, ordering of equipment, nursing care, administration of anesthesia, and even the X-ray and lab work is not done by doctors. Yet, today's doctors do not see these services as an intrusion on their practice, they regard them as essential. The scientist who is attempting to do all this with no advice from people in related professions is leaving the care of animals to reluctant, untrained students because there is some ancient superstition that specialized support is not necessary. In this we are not necessarily advocating a complete centralization on the local level but a professional look at the situation, taking advantage of every modern system possible.

The scientists should welcome a center which would deliver information to professional researchers. Resistance to this idea is as archaic as the battle against nursing care for soldiers at the front during the Crimean War. In the modern fight against disease we need all the professions possible on the front line. We suspect that in our own time we did not go to the moon without a respectful attitude toward members of the many professions on the team. We believe there are wise scientists on the inside and thousands of decent people on the outside who can believe that this is an idea whose time has come.

A second essential for efficient research is proposed in the Research Modernization Act (H.R. 556) which would provide for a Center for Alternatives. Anyone who is enjoying the alternative of the vacuum cleaner instead of the broom, or the electric chain saw instead of the axe, can understand the advantages of new alternative techniques in science. The Center for Alternatives would accelerate research and promote the use of alternatives by requiring those who receive grants for experiments to review the available alternatives. However, there is no attempt to force scientists to use alternatives that are inefficient. They merely consider the new methods before choosing the procedure they will use.

The Center would include representatives from the Government agencies concerned with research. This places the promotion of alternatives in the center of the scientific community where responsibility should rest. The bill also recognizes the fact that since Government makes grants for research, it should assume the responsibility of acquainting scientists with alternatives which would be most effective from a scientific and budgetary point of view.

Much of the scientific community has the perception that the Act would obstruct "scientific freedom" and not allow production of comprehensive research results. However, a growing body of scientific literature and thought demonstrates that not only are results comprehensive but that the results are actually more reliable. Many scientists have, in fact, restricted their own freedom through their unwillingness to explore, in depth, the possibilities of alternatives. With research modernization, a new orientation to scientific experimentation would be born. Innovation and change have never hindered science's quest for knowledge before and they won't now.

It is hard to see why NIH is dragging its feet on the valid ideal of H.R. 556. The goal of this bill is to modernize research not to stop it. The bill needs some amendments, which are recommended in the section on alternatives in this statement. The scientific community damages its own image by resisting the promotion of alternatives, since a sensible public, is already in favor of these changes.

This legislation will attract the moderate people among those who respect animals, and the scientists who are eager to have available new ways to solve problems and perfect their findings. Congress, which is always looking for practical improvement and economy, and above all, for a consensus, should support this measure in place of more radical legislation or continued neglect of the subject.

We hope that Congress will see the benefits of both a Central Animal Care program and a Center for Alternatives. This is not just "an animal cause" but would be welcomed by the best of the scientific community as a way of minimizing variables and improving the methodology of research. These proposals offer a common ground for those on both sides of the issue to make progress toward their different goals.

WE NEED A BYPASS OPERATION

For the sake of economy, valid research and a sincere active ethic, the federal research establishment needs a bypass operation. The local research centers should be able to get help from central information centers on animal care and alternatives. Now this help is mired down with the overloaded ineptness of USDA, the indifference and confusion in DHHS, NIH, and the lack of organization in their local centers. This lack of central help in the medical establishments leaves a shameful vacuum. After 27 years, we are convinced of this. Along the way we have found many dedicated intelligent people who deserve a rewarding way to help inside and outside of research.

SITUATION IN USDA

The USDA Animal Welfare Program was created to enforce the Animal Welfare Act. Unfortunately, the program has not been effective in carrying out its mission. In addition to inspecting research centers, it is responsible for animal breeders, dealers, and to a limited extent, pet shops. It is expected to regulate airlines and surface traffic. USDA's primary focus with regard to animals is the inspection of livestock to prevent disease. This is a far cry from the research environment where USDA inspectors are looked upon as unprofessional invaders. Scientists respond only to their own peer group influence. WARDS interviewed two veterinarians in charge at research centers to get their opinion of the USDA service. They said:

> "USDA needs a major overhaul and facelifting. Everyone thinks it's a joke. AALAS (The American Association for Laboratory Animal Science) never would have had to exist if USDA had done its job."
>
> "USDA has the credentials on paper, but very little experience around the research community. Their people come into facilities and say they haven't been trained, and do not know as much as 'you do.'"
>
> "USDA inspections are haphazard; they don't see anything. One man brought his wife, he was too old to carry things. They should hire young people just out of school and pay them well enough."

In addition to low-quality inspections, the USDA record of legal enforcement by prosecution has been poor. In its 1980 annual report, USDA states that out of over 1,200 apparent violations, the agency prosecuted 20 cases. A study of the outcome of each of these cases would reveal further the problems faced by the USDA's overloaded and varied programs.

Dr. Pierre Chaloux, USDA Deputy Administrator for Veterinary Services, met with Humane organizations just prior to his retirement and made the following points regarding USDA's performance on the Animal Welfare Program.

Animal welfare programs are not a priority within the Agency:

The Animal Welfare Program is expected to do a $20 million job with only $4 million. The 1981 budget has not been increased to encompass inflation and additional duties.

The Program must compete with human welfare programs that have been a well-understood USDA function.

Court cases against violators of the Animal Welfare Act currently take months and sometimes years to prosecute, and the penalties given have been light. Thus, violators do not see legal action as a deterrent to their activities.

Regulated personnel ceilings at USDA make it necessary to place employees who are untrained and uninterested in animal welfare into this new program.

A further problem USDA faces is the enforcement of U.S. Federal regulation CFR, Section 228(a)(4), which requires research facilities to report the number of animals used in painful experiments each year. WARDS opposed this reporting because we realized it was of no practical value. In addition, it was a time-consuming, expensive paper-over of the real situation. To the questionnaires of 1980, 673 centers said they used pain-relieving drugs on 481,716 animals and 165 centers said they withheld drugs from 122,650 animals because of the nature of the research. This is supposed to comfort us. It does not because WARDS realizes this regulation merely encourages the centers to require their veterinarians to sign reports which they know to be inaccurate or false. They may keep their jobs but it compromises their ethics. This reporting of painful experiments is useless paperwork and an unnecessary burden for USDA.

SITUATION IN DEPARTMENT OF HEALTH AND HUMAN SERVICES AND NATIONAL INSTITUTE OF HEALTH

WARDS' goal of professional care of animals in research is not a priority of DHHS and NIH. They refuse to acknowledge that a problem exists. Secretary of DHHS, Patricia Harris, settled the subject in these words:

> "All our institutes must meet standards for humane care and housing specified by the Laboratory Animal Welfare Act.... Moreover, we require our programs and those we support to follow the NIH Guidelines for the care and use of laboratory animals. The NIH Guidelines are more stringent than the Laboratory Animal Welfare Act."

But, in spite of these soothing words, a 1978 survey by the Institute for Laboratory Animal Resources (ILAR) reported that only 14 of the 21 research organizations within NIH itself even claimed to be following the NIH Guidelines. Moreover, out of all the responding laboratories only 77 percent even claimed to be complying with the NIH Guidelines; about half of these 603 laboratories claimed accreditation by the American Association for Laboratory Animal Science (AALAS), although AALAS had approved only 378 laboratories. Out of all the laboratories surveyed, 23 percent admitted they were not complying with the NIH Animal Care Guidelines or refused to answer the question. (For more information on the ILAR, see Appendix 2.)

NIH does not have a workable mechanism for dealing with human subjects in research, much less animals. Its new (1980) Debarment/Suspension from Eligibility for Financial Assistance Regulations were formulated to handle "serious violations involving matters which have important or dangerous consequences." Yet to Congressman Gore's consternation, it was brought out at the hearing of the Subcommittee on Research Oversight, that even these elaborate regulations failed to prevent an abuse as serious as injecting humans with DNA.

Besides debarment regulations, NIH has an alert memo which comes from the office of the Associate Director for Extramural Research and Training (ADERT). It notifies the Director of NIH and the Secretary of DHHS and other appropriate people within NIH that an applicant for a grant or contract is under investigation for fraud or abuse. The investigations are made by the Division of Management Survey and Review (DMSR). DMSR can suspend or terminate grants, if the grantee has materially failed to comply with the conditions of the grant. Unfortunately "material failure to comply" is not clearly spelled out.

In spite of these regulations, NIH has never blackballed a fellow scientist. The way that NIH disciplines or fails to discipline its scientists is not in the area of WARDS' concern. We deplore the failure to protect humans in research but this is a large area we cannot encompass. We introduce these subjects to illustrate the plight of the animals where there is no respect or system for their protection. Problems with the present system of reporting research abuses include:

- There is no formal procedure by which a local institution can report problems with a scientist.
- Institutional Review Boards are not informed. Problems may get to the Dean or the Department Head but never reach the Board because it has not been given power in its institution.
- NIH will continue to fund a scientist "until found guilty."
- Each case is cared for on a different basis.

OFFICE FOR PROTECTION FOR RESEARCH RISKS

The Office for Protection for Research Risks (OPRR) is an effort by NIH to monitor the well-being of research subjects, both human and animal. It requires "assurances" that the center's local Animal Care Committee has reviewed care procedures once a year. OPRR is not empowered to use site visits to verify the information. Without this assurance OPRR is vulnerable to the problems inherent in asking institutions to report on themselves. It involves the natural bias in favor of the center. In addition, it lacks real professional coverage of the situation. (See Local Care of Animals in Research at the end of this section.)

At NIH there are peer group inspections of research sites to assess the scientific merit of a project. Although huge sums are spent on the complicated machinery and operating equipment of research, the inspections do not cover the animals upon which the research is to be based or the environment in which they are kept. WARDS believes that such inspections are a condition of good research although they should be carried out and administered centrally through NIH by experts in the various facets of animal management.

Scientists who serve on the NIH Review Groups (which are a part of the NIH system to award research grants) are comforted by OPRR. At a meeting of the Chairpersons of the Review Groups, one of them said:

> "In my experience the study sections find a considerable amount of their own time and energy saved with the knowledge and the assurance that some institutional process has gone on."*

That disagreements do arise between the Review Groups and the Oversight Committee is evident from an NIH spokesman's statement: "Sometimes we've frankly disagreed about technical and clinical considerations with the institutional review boards." Another one commented that not all institutions have well-established institutional review boards as do the big universities and that NIH must assume responsibility for the oversight function.

WARDS supports the mechanism of peer review in the scientific community. In the hands of professionals inside and outside of NIH, peer review could play a useful role in attaining the goals of quality care of research animals and increased use of alternatives.

LOCAL CARE OF ANIMALS IN RESEARCH

Reform in the care of animals is also necessary at the local level in research centers across the country. A hopeless picture is created by scientists who have no professional background in animal care, the casual interest of the Institutional Committee, the occasional visits of AALAS (The American Association of Laboratory Animal Science), good as they are, and the disorganization of USDA. This is the way layers of paper investigations can oppress a single project and create inefficiency and frustration. The single agency that makes the grants is in the best position to provide a means to monitor the conditions in these local facilities. This is just good business. The local institutions should be responsible for the care they have been paid to provide. Dr. Frederickson made this clear in his testimony in Congress. Up until now NIH has believed that anything more than a "gentleman's agreement" with its grant-recipients would interfere with research. This is not working in business and it is certainly not providing protection for animals in research. What follows is a case study from the University of Iowa which illustrates the confusing regulatory picture.

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*Proceedings of the 1979 Meetings of the Chairpersons of NIH Scientific Review Groups," p. 35.

CASE STUDY: HOW CHANGE FINALLY CAME TO THE UNIVERSITY OF IOWA

BY ANN GONNERMAN, WARDS, FIELD REPRESENTATIVE

At the University of Iowa, the Animal Care Committee performed its annual review and then filed its assurances of compliance with animal care guidelines to NIH's Office of Protection from Research Risks. The USDA Section Veterinary Medical Officer made routine inspections, circled the same deficiencies regularly, inspection after inspection, showing no change from year to year. NIH site visit teams came and went, as they do in every major research facility in the United States, several times a year, ignoring the animal quarters, approving new research which would utilize even more animals, approving grant after grant totaling up into the millions of taxpayer dollars. The animals, housed in unsanitary, hopelessly inadequate, quarters, neglected in every way, were used by the millions.

In July of 1978, the Iowa Federation of Humane Societies was allowed to take a tour of the animal quarters. Two members of that group decided not to look and leave, and they were able after nine months of persistent requests to obtain an inspection by the Animal Care Specialist from the United States Department of Agriculture's Animal and Plant Health Inspection Service, who was newly assigned to the North Central Region. His inspection documented many intolerable deficiencies and violations of the minimum standards of the Animal Welfare Act. The Des Moines Register and Tribune published the facts. The USDA specialist immediately met with the University administration to determine how and when they would come into compliance. The rumor spread that the University might lose its Federal funds. The veterinarian in charge at the University was fired; a new, acting veterinarian was appointed, and the University of Iowa began the slow, painful process of making up long years of neglect and bad research. NIH's Office for Protection from Research Risks (OPRR) was aware of the conditions because Iowa sent an "assurance" which listed the deficiencies, but OPRR took no action because they maintain that USDA is responsible for inspections. There had been no discussion at OPRR of the serious deficiencies, failure to meet guidelines and policies, or possible fraud in the submitted assurances.

It took a miraculous combination of circumstances to bring reform. The two members of the humane society decided not to look and leave after the tour. They found a new USDA specialist who was willing to listen to their account of the situation which he then verified by his visit. The newspapers had the courage to blast a local university for its neglect. The rumor of the loss of funds further convinced the university to take action. The persistent follow-up by the USDA specialist has continued the reform. WARDS believes this proves we cannot always depend on a conversion of lucky breaks to change the terrible neglect of animals in research.

ANIMAL CARE IN RESEARCH

Center for the Environment of Animals in Research (CEAR)

The need for a centralized Federal program for the care of animals is amplified by a few quotes from veterinarians at research facilities who are trying to cope with the Federal disorganization:

> "If one agency could handle standards instead of USDA, NIH and the Good Lab Practices Act, it would be easier for us. We don't know who to respond to; every time we must respond to a different agency. Sometimes they are contradictory. And, anytime there is more than one rule, this is used as a reason not to abide by any of them."

> "When a grant is made, the animal care is the part least scrutinized. They can get away with lots of things. If grants are going to help animals, there must be some way of guaranteeing that it is used for the animals."

> "People who are on both sides of the fence must be able to communicate. There is fear and suspicion on both sides. Who suffers and is frustrated? It is the people who are trying sincerely to change the situation."

The purpose of central animal care is to eliminate as much stress as possible in the use of animals for research. This is no longer a laughable, lost cause of sentimental people but a scientific need which has been amply proved and its impact measured. It has been established that the animal patient in research that suffers stress can cloud the findings of a research project.

Dr. Frederickson said at a recent hearing, "Well designed clinical trials normally provide for alternatives to subjecting (human patients) to unnecessary or burdensome diagnostic procedures in order to satisfy the requirements of protocol." This is exactly what we are asking for the animal in research--that, where possible, unnecessary, stressful handling be avoided.

Dr. Vernon Riley, Chairman, Department of Microbiology, Pacific Northwest Research Foundation, has measured the stress which animals experience under the present routine laboratory procedures. His experiments show how stress weakens and even destroys the immune system, exposing animals to cancer and viral infections. Dr. Riley asks, "How many small animal experiments of the past and present may be seriously flawed because of inattention to the effects of stress in laboratory animals?" He called for a reassessment of the current laboratory animal standards and techniques related to animal experimentation. Riley's stress experiments showed that mice partially protected from stress showed less than 10 percent of cancer tumor incidence at 13 months of age compared to 92 percent to 68 percent, respectively, in unprotected groups. Another authority raises this same concern in his article "Why Painful Experiments and Lack of Proper Animal Care are Scientifically Undesirable." He writes, "The stressed animal is not normal either biochemically or physiologically." These findings make the unstressed animals an absolute necessity.

In a Congressional hearing on the land grant college it was brought out that money was given for research but nothing was designated for animal quarters. One Congressman asked, "How is research being carried out where research facilities are so scarce or inefficient?" Quality animal care is measurable, and should be documented in terms of the number of animals, space allowed per animal, and personnel available.

A major function of a central animal care center would be to strengthen the position of veterinarians in charge of animal care in research facilities. Congress wisely put these men and women in these positions to provide expertise in the speciality of animal care.

WARDS interviewed a veterinarian in charge of a research facility. He stated:

> "I have good top support at my Center. The Dean wants a good facility. Many facility administrations don't provide that support. The Dean and the Vice President must be behind you. Vets are in trouble in some of these places. One of the Big 10 Universities was using material most would call a bio-hazard. They refused to listen to the vet and the administration would not support him."

WARDS believes that the authority and responsibility of these veterinarians in the area of animal care must be clarified. Research is suffering from failure to make proper use of these professionals.

It is premature to talk about the exact structure and duties of the Animal Care Center. It must have the input of ILAR and AALAS. It could operate in the single goal pattern of the Food and Drug Administration, using highly trained personnel to work directly with the local research centers. Primarily it would be responsible for the design and maintenance of a healthy environment for the animals in research. It would support research into stress-free animal care, and the selection of appropriate animal models for research. The Center would also provide a central source of information and can borrow ideas from the National Cancer Institute and other institutes as to methods of making findings useful.

Such a center, dealing directly with the local research facilities, would bypass the present expensive confusion of the many departments at NIH while making available information on the valuable work already being done at NIH and other places.

A CENTER FOR ALTERNATIVES

WARDS supports the modernization of research through the use of alternatives, and the creation of a Center for Alternatives at NIH, which is provided in H.R. 556. The Center would be modeled on the various independent health institutes under the NIH umbrella, and it would have as its single goal the promotion of alternatives in research.

Currently, there is some evidence that NIH is trying to find substitutes for animals in research, but the efforts are scattered and modest in scope. The Laboratory Animal Science Program provides grants to define animal models, and this would reduce the waste involved in using an inappropriate species. The Institute of Environmental Health Sciences focuses on the methodology of good research. It is trying to improve toxicity tests which are currently "expensive, time-consuming, insensitive, and require costly professional staff time."* This division is also exploring the problems involved in extrapolating the results of tests on animals to man. Scattered throughout NIH's 11 Institutes, seven or more divisions of supporting services, and 46 buildings, there is a great deal of information on alternatives which must be made accessible if it is to be used. A Center for Alternatives would provide an information service modeled on that of the National Cancer Institute, which would make on-line data on alternatives available to veterinary and medical schools.

*1981 NIH Almanac, p. 111.

The use of alternatives can be open to endless arguments, but must finally rest on the judgment and will of the scientist. Only through the intelligent interest and consent of the individual scientist will research modernization occur. The Center for Alternatives would organize the information on alternatives and educate scientists in their use. It should be free from any sense of coercion. This new Center would foster the idea of alternatives until the value of these new systems for research is understood. The Center would be staffed with specialists in alternatives who could demonstrate and promote their use. Qualified people would be encouraged by grants to continue the exploration of alternatives.

The Center should not require any new elaborate scientific buildings or other expenditures. The only space necessary would be for a small central office within NIH to collect and disseminate information.

WARDS proposes two amendments to H.R. 556. First, that the subject of duplication will be dropped from the bill. As proposed, the bill seeks to "eliminate or minimize duplication of research and testing on live animals." WARDS feels that this goal distracts from the subject of alternatives, and that the idea of duplication in research is already being dealt with by at least two agencies, the Smithsonian and the National Library of Medicine. For years, WARDS has tried to bring some action to the subject of duplication. It is an important need of research, especially now that the public is aroused and concerned, but we must not burden the Center with trying to be all things to all people.

With regard to funding, the bill proposes that no less than 30 percent and no more than 50 percent of an agency's research budget must be directed to the development of alternatives. However, WARDS prefers to treat funding in the same way we do for the Animal Care Center. We would submit a carefully planned budget each year. This would permit the Center to grow naturally. A large static fund might be too much the first year and not enough for some other year.

WARDS' primary commitment is to prevent animal suffering wherever possible and to stop the staggering, useless, waste of animals where alternatives can be substituted. Congress should make possible the organization of this important subject. It is a modern economy move.

(Further information on alternatives in Appendix 3.)

APPENDIX 1

Breakthrough for Prevention of Stress

EXACT MEASURE FOR STRESS FOUND

There is a practical scientific breakthrough that should stop some of the unnecessary stress in animals in research. Dr. Vernon Riley, Chairman, Department of Microbiology, Pacific Northwest Research Foundation, has discovered that protective housing and handling of mice can eliminate stress and preserve their immuniological apparatus so they are able to defend themselves against infectious agents and many disease processes. He has perfected a means of measuring the extent of stress with a clearly defined process. This takes the evaluation of degenerative suffering of animals out of the realm of speculation or elusive subjective description. Through his procedure the smallest degree of stress can be perceived almost instantly, creating a repeatable MODEL of exactness.

Stress factors are extremely important in designing an experiment. Dr. Riley says, "A troublesome aspect of earlier studies was the failure of the investigator to appreciate the extreme sensitivity and rapidity of the physiological alterations occurring in animals exposed to experimentally or environmentally induced stress. In mice, critical phases of the stress syndrome are initiated immediately after the slightest disturbance. The physiological consequence of this stress may continue for hours or days depending on the nature, severity and duration of the stimulus."

The problem in measuring stress has been to arrive at "authentic quiescent baseline conditions for experimental animals." This has complicated the interpretation of some of the earlier studies. "Consequently, results between laboratories tend to be inconsistent, undermining confidence in the reliability of research in this field." He points out that rapid developments of new facts of immunology, endrocenology and neurobiology can further close the gap toward exact findings.

Dr. Riley further pointed out that "Although it may be hazardous to extrapolate biological findings from mice to other species, it would be equally impudent to ignore the many physiological similarities and analogous biochemical relationships that evolutionary biologists have demonstrated in animals belonging to the same phyla. Thus, fundamental biological principles that are further delineated through the study of animal models may be expected to have application to man."

Dr. Riley has found that "the rapidity of physiological response to handling induced anxiety stress is indicated by measurable increase in plasma corticosterone within less than 5 minutes after the animals have been agitated by simple capturing proceedings. The difference between stress in a conventional holding area for mice and an enlarged protective system was easily measured."

It is necessary to eliminate vibrations and rumblings of centrifuses, vacuum cleaners and heavy equipment. There must be protection from all drafts and air turbulence. There is need for a planned lighting system. In addition, transistor radios and loud voices disturb these animals. Chirping sounds between mice in open cages can be a means of spreading distress signals. Enclosed shelves provide a substantial amount of soundproofing from many alarming signals. With regard to segregation, it was established that males and females should be separated in different areas to prevent odors from being transmitted.

The rapidity of the physiological response to handling-induced anxiety stress is indicated by measurable increase in the plasma corticosterone quickly after the animal has been agitated by capture. It starts when the animals are transferred from the protective shelves. This means there must be a rigorous time limit in the system of handling these animals for any research process.

Dr. Riley has found a simple straightforward way to detect stress. This is an important measurement in a research plan because differences here can affect the outcome. If there is a latent cancer virus in the body, a defect in the defense mechanism could permit the disease to spread. This could be brought on from severe acute stress, from mild chronic stress, or intermittent stress. If an experiment is to be validated there must be a uniform, accurate way to arrive at the answers or humans will suffer and millions of animals will be wasted.

APPENDIX 2

ILAR NATIONAL SURVEY OF LABORATORY ANIMAL FACILITIES AND RESOURCES

The Institute of Laboratory Animal Resources organized a survey of U.S. research laboratories in 1978. Although it is subject to problems of interpretation which site investigations would eliminate, it provides a useful overview of the problems and trends.

> ILAR found that there was a failure of laboratories to achieve peer evaluation through AALAS accreditation. Although 603 labs claimed accreditation, AALAS has only accredited 378. ILAR raised the question of why 370 of the labs which had planned to become AALAS accredited in 1968 had failed to do so by 1978.
>
> ILAR discovered "acknowledged noncompliance with the DHHS guidelines . . . especially among DHHS respondents," and found this "obviously a matter of concern to most granting agencies in evaluating requests for research funds." ILAR

recommended that "the basis for this noncompliance needs further evaluation."

ILAR found an 18 percent increase in veterinarians specializing in laboratory animal medicine in the 10 years since 1968. However, their information suggests "substantial involvement in activities other than service, especially for professional personnel."

ILAR reports a decrease in the number of laboratory animals acquired during the last decade except for swine, rodents, horses and cattle, but it reports an increase in the average length of stay. This suggests an increase in long-term studies.

ILAR found that although laboratory animal facility space had increased by 2.5 million square feet since 1968, the accounting does not distinguish between space in which the animals are used, versus space for their comfort and housing.

ILAR reports that 250 research centers have stated the need for new construction to contain biohazards.

ILAR reports a real decrease in expenditures for animal food and care costs.

ILAR recommends centralization of animal care programs within the research organization as the most efficient and inexpensive method. The survey found a decrease in the existence of centralized facilities in the last decade, with 54 percent of the labs centralized in 1968, and only 48 percent in 1978.

ILAR recommends financial accountability for animal care programs. User fees, one method of apportioning direct costs to research projects, have not been used sufficiently or in a consistent manner too ensure good management of animal resources.

ILAR reports that "The majority of respondents who acquire animals from their own breeding sources do not maintain genetic records, and that these in-house animals are more expensive than those from commercial sources. ILAR recommends careful maintenance of genetic records and the use of commercial sources for animals.

While supporting the recommendations of ILAR, WARDS further proposes:

Professional Standing:

A veterinarian with a staff should be in charge of animal care at each institution. He should have the necessary authority and professional standing to accomplish this task.

Cost Accounting:

The cost accounting for "Animal Facilities Space Needs" includes expensive equipment for the use of animals, but brings little health or comfort to them. It is incorrect to describe this use of funds as animal facilities. When this distinction is made, it is very clear that very little is even being requested to improve the life of the animals.

Biohazards:

This dangerous work should be carried on by a few specialized research centers equipped and ready to take the detailed precautions necessary for this work.

Effects of Stress:

More attention should be paid to high quality care to lessen the effects of stress resulting from a substandard environment, as this might affect the outcome of the study.

APPENDIX 3

ADVANTAGES AND DISADVANTAGES OF TISSUE CULTURE

W.M. Dawson, Department of Pharmaceutical Technology, University of Shaythclyde, Glasgow, has outlined the following:

ADVANTAGES

1. Eliminates errors about species difference. Species difference can occur at the cellular level as well as in whole animals.
2. A range of cell types can be used and thus differences in effect may be noted.
3. Application of tested substance is direct, often eliciting rapid results.
4. Often, the effect can be measured quantitatively.
5. Smaller amounts of the drug to be tested are required.
6. Materials (e.g. radioactive materials) potentially harmful to humans and animals can be studied.
7. Cellular material may be kept frozen.
8. Cells can be used in different countries, leading to better comparison of findings.
9. Main advantage to the manufacturer is cost.
10. Replicate experiments can be performed in statistically significant numbers.

LIMITATIONS

1. Can detect drug effects only if the drug acts directly on or in a cell.
2. Inapplicable to substances metabolized *in vivo*.
3. Inapplicable to drugs acting on multi-stage physiological systems.

4. Teratogenic (reproductive) defects cannot be directly studied *in vitro*.

5. Behavioral effects cannot be directly assessed.

APPENDIX 4

SOURCES

National Institutes of Health, Proceedings of the 1979 Meetings of the Chairpersons of NIH Scientific Review Groups (Fall 1979).

U.S. Department of Health and Human Services, 1981 NIH Almanac (1981).

U.S. Department of Health and Human Services. National Survey of Laboratory Animal Facilities and Resources (1978).

U.S. Department of Agriculture. 1980 Animal Welfare Enforcement; Report of the Secretary of Agriculture to the President of the Senate and Speaker of the House of Repesentatives.

Subcommittee on Department Investigations, Oversight and Research Committee on Agriculture, House of Representatives, July 29, 1980.

Submitted September 20, 1981.

STATEMENT OF STUART E. PROCTOR, JR., ASSISTANT DIRECTOR, AMERICAN FARM BUREAU FEDERATION

The American Farm Bureau Federation is the nation's largest voluntary general farm organization with over 3.2 million member families in 48 states and Puerto Rico.

Farmers have the enviable reputation of being compassionate stewards of their livestock. Our members are interested in the humane treatment of all animals. Despite our documented concern for the treatment of animals, we are currently under the attack from a number of associations and individuals who make inaccurate and misleading statements about the treatment of farm animals. Their intent is to make major reforms in livestock production practices in this country using emotional arguments, examples, and generalizations to fabricate a problem where one does not exist.

We are concerned that some of these same tactics are being used to describe the treatment of laboratory animals. We question whether Congress has been presented with sufficient evidence to substantiate the need for corrective legislation. Congressional action to legislate and regulate in this area is inappropriate unless evidence is presented which shows a problem. Without such evidence, Congress is being asked to overract to undocumented problems. We must remember that animal research is being conducted for the benefit of mankind. Unnecessary laws and regulations which could obstruct this research must be avoided.

In order to provide the data necessary to make legislative decisions concerning the regulation of laboratory animals, Farm Bureau supports the National Academy of Science study outlined in S. 964. Legislative action is premature without thoroughly assessing how animals are currently being used in research. This study will provide an independent evaluation of this issue in a short period of time.

The need to further investigate the seriousness of the laboratory animal problem appears to be gaining wide recognition in the Senate. In report No. 98-110 on the Biomedical Research Training and Medical Library Assistance Amendments of 1983, the committee on Labor and Human Resources states:

"It is presently unclear just what the extent of the problem may be in federally funded research facilities. Proposals to upgrade animal laboratories to meet certain standards could prove very costly, perhaps diminishing the overall research effort. It is also not clear what alternatives to the use of animals should be promoted. In light of these uncertainties, the bill provides for a comprehensive assessment of the current status of the use of live animals in research. The 18-month study will provide the Congress with information necessary before considering any further Federal legislation."

In report No. 98-160, the Committee on Appropriations states: "The Committee is concerned about the effectiveness of current enforcement of the Animal Welfare Act. In that regard, the Committee will request that GAO conduct a study of the enforcement of the act to be provided to the Committee prior to submission of the fiscal year 1985 USDA budget."

This wording implies there may be an enforcement problem that could be corrected by administrative action and increased funding rather than by legislative action.

In view of current efforts by farm and laboratory animal welfarists to seek legislation for emotional reasons, we are concerned there will be future attempts to apply Animal Welfare Act regulations to agricultural research. The need for the agriculture exemption is well substantiated and incorporated in the original version of the Act.

We are concerned about humane treatment of all animals, including laboratory animals. It is important that all evidence describing the situation is accumulated before legislative action is proposed.

STATEMENT OF JOHN F. KULLBERG, ED. D., EXECUTIVE DIRECTOR, AMERICAN SOCIETY FOR THE PREVENTION OF CRUELTY TO ANIMALS

The American Society for the Prevention of Cruelty to Animals (ASPCA) is in support of S. 657, an amendment to the Animal Welfare Act that would require the use of the lowest number of animals possible in any experiment, encourage the use of alternatives, avoid repeated operations on the same animal, curb abuse of paralytics and provide improved oversight by requiring each institution using laboratory animals to include on a review committee at least one member from outside the institution to be responsible for community animal welfare concerns.

The ASPCA has long been involved with other humane organizations in seeking both a reduction of the number of animals used in scientific experiments and the development of alternatives to animal use. Our joint efforts have been rewarded with some positive results:

The Director of the National Toxicology Program recently admitted that the LD_{50} test is an anachronism.

The U.S. Senate passed an amendment just last year directing federal agencies to set aside time and money to find alternatives to the Draize rabbit eye test.

The Director of the National Center of Toxicological Research has committed the Center to the development of alternative model systems to wholesale animal testing.

Bristol Myers has committed itself to significantly reducing the numbers of animals used in tests and, where possible, to use non-animal tests.

Revlon is now using computers to identify products with similar formulas in order to avoid duplication of testing and has significantly reduced its use of animals even as its overall cosmetic production continues to increase.

Johnson & Johnson now uses a cell culture test as a preliminary screen for potential irritants.

Avon reduced its use of live animals in 1982 by one-third.

Johns Hopkins University, Rockefeller University, the University of Texas and other major learning and research centers are seriously pursuing through well-financed programs development of alternative measures to live animal research. Much of the funding for these efforts is coming from corporations and other members of the research community.

While all of these foregoing examples of successes in reducing the numbers of animals used in research are indeed heartening, without significant and strong direction from Congress now, these joint efforts for a more humane and caring and no less effective process of scientific inquiry may be quickly dissipated. Dr. Alan M. Goldberg, Director of the Johns Hopkins Center for Alternatives to Animal Testing, recently noted that for the first time in our history government, industry and the concerned public have spoken in unison on the need to not only reduce greatly the number of animals used in scientific tests conducted by industry to satisfy government regulations on toxic substances but also at the same time to have an all-out effort to seek alternatives to the use of animals.

S. 657 not only incorporates recommendations for the development of alternatives, but also requires animal studies committees in each research facility to include a veterinarian and a member, not affiliated with the institution, primarily responsible for representing community concerns regarding the welfare of the animal subjects. These animal studies committees would make semi-annual inspections and review research methods and practices to ensure compliance with established standards. Lack of compliance with these standards could lead to loss of government funding.

The need for animal studies committees is great. Under the Freedom of Information Act we have seen USDA inspection reports of medical schools and other scientific institutions and have determined that although more might have been done to protect animals from unscrupulous or insensitive researchers, enough has been done to justify on humane grounds the existence of such committees.

Other inclusions in S. 657 are reassuring to those of us who wish to see more humane standards in laboratory research. These include provisions that would prohibit an animal being used more than once in a major operative procedure except for scientific necessity or a special circumstance that would be approved by the animal studies committee; a requirement that the principal investigator consider possible alternative methods to any procedure likely to cause pain or distress and to consult a doctor of veterinary medicine in the planning of any such procedures; a requirement to make proper use of tranquilizers, analgesics and anesthetics; a requirement to provide appropriate pre- and post-surgical medical and nursing care; a requirement to provide adequate anesthesia if paralytics are used; and a requirement to withhold pain killers or euthanasia no longer than is scientifically necessary.

I am also pleased to see that language in the current Animal Welfare Act requiring "minimum standards" for care and housing of animals would be changed to "proper standards," to include adequate exercise. S. 657 also protects employees from discrimination for reporting violations of the law which they may observe. One may have study committees and substantially funded governmental investigators enforcing Congressionally approved human standards, but so much experimentation is going on today that sufficient oversight from the outside is just not possible. By protecting so-called "whistel blowers" the Senate establishes a laudatory and important public—and animal--protection norm. The establishment of an information service at the National Agricultural Library is also a very encouraging inclusion in S. 657 so that information and methods reducing or replacing animal use, minimizing pain and distress, and preventing unintended duplication of animal experiments can be accessible to research scientists and animal studies committees.

As the senior spokesperson for The American Society for the Prevention of Cruelty to Animals, America's first humane society, I strongly urge passage of this very important humane legislation. It will not please all members of the scientific community nor all humane groups. Compromises have been made and areas within the bill that would be greatly enhanced with significant funding, particularly for the development of alternatives, do not exist. Nonetheless, all things considered, S. 657 will greatly strengthen the Animal Welfare Act by providing a more humane environment for research animals today while we continue to seek ways of improving their welfare in the future without seriously inhibiting the humane goals of the research community. Scientific advancement and humaneness toward animals are compatible. S. 657 enhances this compatibility.

PSYCHOLOGISTS FOR THE ETHICAL TREATMENT OF ANIMALS,
Lewiston, Maine, August 1, 1983.

Senator ROBERT DOLE,
Hart Senate Office Building,
Washington, D.C.

DEAR SENATOR DOLE: On behalf of the growing number of psychologists concerned with animal welfare I am writing in support of S. 657. This bill embodied a consensus of present views of both the animal welfare and the scientific communities. Recent trials and exposes in both research and commercial testing settings demonstrate that legislative action is required. This is not a time for further study.

As a group of psychologists vigorously attempting to have impact on the practices in our own field, we particularly endorse among the provisions of S. 657 the inclusion of an outside member on institutional animal care committees, the establishment of a central information service to promulgate information on "alternatives" and to decrease duplication in research, and protection of employees who report violations.

Please include these remarks in the record of the hearings.

Sincerely,

KENNETH J. SHAPIRO, Ph. D., A.B.P.P.

AMERICAN VETERINARY MEDICAL ASSOCIATION,
Washington, D.C., August 10, 1983.

Hon. ROBERT DOLE,
U.S. Senate,
Washington, D.C.

DEAR SENATOR DOLE: We would appreciate having this letter made a part of the record of the July 20, 1983 hearings of the Senate Committee on Agriculture, Nutrition, and Forestry on S. 657. The American Veterinary Medical Association supports the basic intent of the bill. We have for some time expressed the opinion that the Animal Welfare Act should be adequately enforced before other legislation is considered. We have encouaged appropriate funding for that purpose. We believe S. 657 will strengthen the Animal Welfare Act, which is a desirable step to take.

We recommend modest revisions of the bill to clarify the intent and aid in its enforcement. We also recommend deleting the paragraph beginning with line 3 and ending with line 7 on page 8. If we may be of assistance in making a few revisions in the bill, we will be pleased to discuss our suggestions with your staff.

Sincerely,

W. M. DECKER, D.V.M.,
Washington Representative.

NATIONAL PORK PRODUCERS COUNCIL,
Des Moines, Iowa, July 15, 1983.

Hon. ROBERT DOLE,
U.S. Senate, Hart Office Building,
Washington, D.C.

DEAR SENATOR DOLE: The National Pork Producers Council has considered carefully what position, if any, should be taken in regard to S. 657. After careful deliberation, it is our conclusion not to adopt a position of support or opposition to this bill.

NPPC does not consider this legislation to be of direct concern to pork producing families in the U.S. We are reassured by the fact that this bill would amend the Animal Welfare Act, which specifically excludes farm and food producing animals from its jurisdiction. Your announced support for exclusion of farm and food animals is appreciated. The Council will carefully monitor developments pertaining to this legislation. If efforts are made to in some way include farm and food producing animals, NPPC will be obligated to vigorously oppose any such amendments.

Your interest in the viewpoint of pork producers in regard to this legislation is appreciated. We hope this expression of our position and interests is helpful to you and your cosponsors.

Sincerely,

ORVILLE K. SWEET,
Executive Vice President.

NATIONAL CATTLEMEN'S ASSOCIATION,
Englewood, Colo., July 19, 1983.

Hon. ROBERT DOLE,
U.S. Senate,
Washington, D.C.

DEAR SENATOR DOLE: The following comments reflect the views of the National Cattlemen's Association pursuant to S. 657, in which certain amendments to the Animal Welfare Act are proposed. As caretakers of animals, cattlemen are naturally concerned with animal welfare. In addition to our humane interest in animal care and comfort, we have an economic interest as well. It is our belief, based on experience and scientific evidence, that our dual interests in this subject are not contrary to one another but, rather, are quite compatible. We have resolved to address this issue in a rational and scientific manner.

The National Cattlemen's Association is pleased that you have not included farm animals under the umbrella of S. 657. However, we are concerned that a precedent is being established which could undermine the future vitality of biological research in general. Scientists in all disciplines follow an orderly pattern of investigation. They first identify the problem and then proceed to derive solutions. Attempting to solve a problem before it is defined invariably leads to poor solutions and typically leads to a poor definition of the problem "after the fact." We are concerned that the "committee" established under S. 657 would be attempting to derive solutions to a problem without the benefit of knowing what the problem is.

A final concern regards the section of the bill which discusses the development of in vitro biological models to use as alternatives to experimentation of live animals. We agree that the development of such models would be very beneficial to the research community. We also believe that your intent is simply to encourage their development rather than legislate their use. However, we are concerned that this intent may be taken out of context by many who are less informed on the subject. It would be very irresponsible to legislate the use of in vitro models before they are developed. In fact, it is likely that many experiments will never be able to rely entirely on alternatives to live animal experimentation. We are confident that in vitro models will be developed as part of the orderly progress of science and will not require legislative decree.

We appreciate your interest in animal care and hope that you will consider our comments as constructive criticism since that is our intent.

Sincerely,

TOM GUSTAFSON,
Chairman, NCA Subcommittee on Animal Care.

STATEMENT OF VIRGINIA CHIPURONI, PRESIDENT, THE HUMANE SOCIETY OF NEW YORK

The Humane Society of New York is concerned with the welfare of all sentient animals, and urges the enactment of Senator Dole's bill S-657, which would offer protection to those species used for experimentation.

Because of our own experience with companion animals in our shelter, we are keenly aware of the importance of adequate exercise, especially for the emotional well-being of the animal. Experimental animals, under greater stress than our animals and kept in cages almost certainly smaller than those used in our shelter, need to have exercise and socialization all the more.

From experience in our veterinary clinic and hospital, we know the importance of pre-surgical and post-surgical medical and nursing care, and the use of anesthesia, analgesia, and tranquilizing drugs for adequate veterinary care.

We feel that the provision for having a spokesman for the experimental animal included in the Institutional Animal Studies Committee is a vital one. Conditions in Dr. Taub's laboratory point up the need for at least one member of the animal studies committee whose primary concern is the welfare of the experimental animal subjects. The provisions for regular inspections and reports and the incorporation of minority views are excellent and essential.

The Humane Society of New York applauds also the constructive steps toward increasing the use of alternatives and preventing unnecessary duplication as represented by the provisions for instituting courses and for establishing an information service at the National Agricultural Library.

Finally, the provisions for assurances of compliance are important They should help to decrease pain and suffering, due not to scientific necessity but to carelessness, thoughtlessness or indifference.

This long overdue legislation should be enacted without delay.

One day, we hope, there will be alternate methods that will entirely eliminate the use of experimental animals, but until then, legislation like this is badly needed to help protect them.

SOCIETY FOR ANIMAL PROTECTIVE LEGISLATION,
Washington, D.C., July 26, 1983.

MS. DENISE L. ALEXANDER,
Committee on Agriculture, Nutrition, and Forestry,
Russell Senate Office Building,
Washington, D.C.

DEAR MS. ALEXANDER: I am forwarding several resolutions sent to us by interested organizations which we hope you will insert into the record of the hearing on S. 657.

Thank you.

JOHN GLEIBER,
Executive Secretary.

Enclosures.

LYCOMING COUNTY S.P.C.A. AUXILIARY,
Williamsport, Pa., June 15, 1983.

RESOLUTION OF SUPPORT

We, the members of the Lycoming County Society for the Prevention of Cruelty to Animals Auxiliary, affiliated with our local humane society and formed for the purpose of aiding such society in their efforts to raise funds for day-to-day operation, want it to be known that, individually and as a group, we strongly support bill S. 657, introduced by Senator Dole, and which is designed to eliminate pain and suffering in laboratory animals and to encourage the use of alternatives to living animals in research. We are in complete agreement with the provisions of Senator Dole's Bill and urge its favorable consideration and passage at the soonest possible time.

ARDNA NOLL, *Cochairman.*
JUSTIN MARR, *Cochairman.*
JANE PFLEEGOR, *Secretary.*

ANIMAL RESCUE FOUNDATION,
Middlebury, Conn., June 9, 1983.

SOCIETY FOR ANIMAL PROTECTIVE LEGISLATION,
Washington, D.C.

FELLOW HUMANITARIANS: At its June 8th meeting, the undersigned members of the Board of Directors of the Animal Rescue Foundation, Greater Waterbury-Bristol, Connecticut area, passed a Resolution of Approval of S. 657. The Animal Rescue Foundation is a volunteer organization whose members are dedicated to the care of homeless cats and dogs and the humane treatment of all animals. We urge the passage of this legislation.

Sincerely,

Mary Ann Piché, Secretary, Stuart Hutchins, Therese Wylie, Ginny Donnelly, Charles E. Corr, Gary Koval, Debbie Catuccio, Robert L. Piché.

DEFENDERS OF ANIMALS, INC.,
West Allis, Wis., July 10, 1983.

To Whom It May Concern:

After reading the aims of Senator Dole's bill to protect animals, I am pleased with the approach to curb unnecessary pain and suffering of laboratory animals.

Therefore, support is given to S. 657.

Very truly yours,

RUTH MCCLOUD,
President.

THE ORLANDO HUMANE SOCIETY, INC.,
Orlando, Fla., July 27, 1983.

DENISE L. ALEXANDER,
Chief Clerk, Committee on Agriculture, Nutrition, and Forestry, Russell Senate Office Building, Washington, D.C.

DEAR MS. ALEXANDER: On behalf of the 6,000 plus members of the Orlando Humane Society, I would like to go on record as supporting S. 657.

No one in the humane movement is against all animal testing; just that which is repetitive and in many cases useless, such as LD 50 which is not scientifically justified but is still required by many governmental agencies.

This goes on and on, the problem being there is no one to press the"stop" button.

Senate bill 657 will go a long way toward achieving this most important and desirable action.

Sincerely,

DICK MYERS, *President.*

HUMANE SOCIETY OF ROCHESTER AND MONROE COUNTY,
Fairport, N.Y., July 28, 1983.

DENISE ALEXANDER,
Committee on Agriculture and Forestry,
Russell Senate Office Building,
Washington, D.C.

Re: Support of Senate bill No. S. 657.

DEAR COMMITTEE MEMBERS: May I call your attention to S. 657 and, like my fellow colleagues in the humane field, urge you to support its passage.

The additional advantages that this legislation add to our animal welfare act promises adequate housing and care for animals used in research. Until alternatives can by provided, this will alleviate a lot of pain, stress and unnecessary suffering in this area.

Please help pass this important legislation introduced by Senate Dole.

In advance, my sincere appreciation and thanks.

Sincerely,

FRANK M. ROGERS,
Executive Director and Chairman of the Board,
New York State Humane Association, Inc.

THE ENDOCRINE SOCIETY,
Bethesda, Md., July 29, 1983.

Senator ROBERT J. DOLE,
Hart Senate Office Building,
Washington, D.C.

DEAR SENATOR DOLE: On behalf of the Endocrine Society, I am submitting this statement concerning the use of laboratory animals in biomedical research in response to your request on July 20 for further comments.

The Society represents over 4,000 scientists and physicians devoted to the study of endocrinology. We join you in your concern over the proper treatment of research animals. As research scientists, our concern goes a step further: humane treatment of laboratory animals is essential to accurate research results. Animals receiving improper feeding, housing or exercise will seriously skew research data, thus destroying the project results.

On March 2, 1983, you introduced S. 657 to amend the Animal Welfare Act to ensure the proper treatment of laboratory animals. Although we agree with the intent of the legislation, we feel that this is not the proper avenue to travel. Rather, we believe S. 964, introduced by Senators Hatch and Kennedy on March 24, 1983, is the more prudent route to take at this time. This piece of legislation, which has been incorporated into the NIH Authorization Bill, directs the Secretary of HHS to conduct a study concerning the use of live animals in biomedical research. This sweeping, comprehensive study would provide Congress with information, which is presently unavailable, concerning the status of the use of laboratory animals in biomedical research and would review existing state and federal statutes and regulations governing their use.

To legislate at this time, without support of reliable data, is, we believe, premature. The use of laboratory research animals has been a subject of much discussion: advocates assert that no abuses occur; detractors, on the other hand, believe such abuses are widespread. We believe that, before a legislative mandate issues, the specific problems must be identified. For this reason, we stand in support of the so-called Hatch-Kennedy study. Through this study, data can be collected concerning the use of laboratory animals, from which educated decisions can be made as to what legislation, if any, is necessary.

It is for this reason, on April 8, we joined 61 organizations concerned with biomedical research in a letter to your colleagues urging their support of the Hatch-Kennedy study. A copy of the letter is attached. Since that time, 20 more organizations have joined onto the letter.

We urge you to reconsider moving forward with your legislation until Congress is equipped with reliable data which would be generated from the study provided for in S. 964.

Respectfully submitted,

CLAUDE MIGEON, M.D.,
Chairman, Public Affairs Committee.

Enclosure.

APRIL 8, 1983.

DEAR SENATOR: Senator Hatch and Senator Kennedy have recently introduced S. 964, "The Animal Research Study Act of 1983," legislation designed to provide a comprehensive assessment of the current status of the use of live animals in biomedical and behavioral research.

The undersigned organizations and their constituencies strongly urge you to cosponsor this important proposal. Collectively, these organizations represent the vast majority of the scientific community concerned with the conduct of biomedical and behavioral research.

Various proposals have been introduced during the past several years pertaining to the care, treatment and use of laboratory animals in biomedical research and testing. These bills have been based on assumptions concerning the current conditions and state-of-the-art surrounding the use of research animals when current and comprehensive data on this subject do not exist. Therefore, an in-depth study of the status of the use of live animals in biomedical and behavioral research is not only desirable, but absolutely necessary as a precursor of appropriate legislation.

Enactment of S. 964 would provide the Congress with the necessary information to determine the need and content of future legislative activities in this very complex and important area by requiring a study of: the number of research animals; the status of laboratory animal accreditation programs; the activities of the Department of Health and Human Services in the area of laboratory animal research; currently existing state and Federal statutes and regulations governing the use of animals in research; and the status and future of alternative research methodologies.

The members of the undersigned organizations are deeply committed to the conduct of research under the optimum scientific and ethical standards and conditions and share the deep humanistic concerns of all other concerned individuals about the very difficult considerations implicit in research of this type. Thus, we strongly believe that the information that could be yielded from such a study is of vital importance. The hearing record on this issue reveals a considerable divergence of opinion on both currently existing conditions and the need for the development of a base of accurate and timely information.

Sincerely,

ACADEMY OF CLINICAL LABORATORY
PHYSICIANS AND SCIENTISTS
(and 83 others).

STATEMENT OF JEAN HARPER, PRESIDENT, LEON COUNTY HUMANE SOCIETY, TALLAHASSEE, FLA.

Our organization, the Leon County Humane Society, Tallahassee, Florida, is in total support of Senator Dole's excellent bill, S. 657, Improved Standards for Laboratory Animals. This bill would do much to relieve the pain and suffering of the laboratory animals by curbing the use of paralytics, avoiding the practice of repeated operations performed on the same animal, and minimizing the number of animals used. The increased use of alternatives seems advantageous to the advancement of science as well as to the humanitarian concerns. Of particular value is the requirement that each institution using laboratory animals appoint a committee, of which at least one member comes from outside the institution and is responsible for community attention to the welfare of the animals to provide improved oversight.

Aside from the protection of millions of helpless animals, S. 657 could save a great deal of taxpayers' money by use of an information service which would prevent needless duplication of experiments and tests.

We earnestly hope our Congress will recognize the need for this long overdue legislation.

SOCIETY FOR THE PROTECTION AND PRESERVATION OF ANIMALS,
Blacksburg, Va., July 23, 1983.

Senator JESSE HELMS,
Chairman, Senate Agriculture Committee,
Washington, D.C.

DEAR SENATOR HELMS: The Society for the Protection and Preservation of Animals would like to go on record as fully endorsing S. 657. We believe this bill is a necessary addition to the Animal Welfare Act. The Animal studies committee established by S. 657 will help to monitor laboratory conditions and maintain a closer eye on the respective animal facilities. An outside member of this committee required by the bill to represent community concerns for the welfare of the animal subjects is of major importance.

Further consideration in our support for S. 657 is based upon the improved validity of research results due to the increased monitoring of animal facility conditions and the resulting improvements in the health and welfare of the animals.

Sincerely,

ROBERT MARKMANN, *President.*

STATEMENT OF SAMUEL M. PEACOCK, M.D., PSYCHOPHARMACOLOGY RESEARCH INC., JENKINTOWN, PA.

As a member of the Bio-Medical Research Community with faculty appointments at both The University of Pennsylvania School of Medicine and The Thomas Jefferson University School of Medicine, I have been active in Neurophysiology Research since 1945 with memberships in the American Physiological Society, American Academy of Neurology and The Society of Biological Psychiatry.

The provisions of bill S. 657 provide an appropriate extension of the coverage of the Animal Welfare Act now in place. It has been my experience based on almost 40 years of research at seven institutions, that the individual investigator and the science administrator, for a variety of reasons, will not be concerned with the humane treatment of research animals. It is not that these people are in-humane, but rather that there is a certain overriding zeal to get the research done, coupled with frequent budget limitations which dictate that funds be spent elsewhere. The citing of endless examples will serve no useful purpose at this time. Suffice it to say that the provisions of this bill will motivate the investigator and the administrator alike to be concerned about the basic needs and comfort of the animals entrusted to them. I sincerely hope that this bill will receive early approval.

Statement of Jay Glass, Ph. D., Pittsburgh, Pa.

As a biomedical research scientist, I full well recognize the necessity for using animals in research. However, I cannot condone the abuses of animals in scientific research. Such abuses occur due to the unregulated state of this activity. In addition, those seeking to protest such abuses have no structure into which such abuses may be reported.

Bill S. 657 is an important step toward holding those who perform abuses accountable. Most importantly, S. 657 establishes a mechanism whereby the abuses of animals can be dealt with in a fair minded way.

As one with first hand experience in biomedical research I urge the passing of S. 657. We owe this bill to all those animals, in the past and in the future, who give their lives so that we humans may prosper.

Statement of Bianca Beary, President, Washington Humane Society

The Washington Humane Society speaks in support of S. 657. This bill makes two common sense points with which all competent, ethical scientists should be comfortable:

1. Inspection of lab animal facilities by the U.S. Department of Agriculture. No one including scientists should be allowed to write their own traffic tickets.

2. Inclusion of a member of the public on the animal care committee on each institution. A good laboratory should have nothing to hide. Public representation will better assure that animal welfare issues are not taken for granted. Taxpayers are entitled to this kind of effective oversight.

In conclusion, good science is humane science. S. 657 makes strides in advancing this concept.

Statement of Alex Pacheco, People for the Ethical Treatment of Animals

S. 657 is needed to prevent the abuses which are causing pain and distress to animals used in experiments and tests throughout the United States.

Neglect and indifference to the well-being of the animals is at the root of much of the suffering. We believe that S. 657 would help to dispell this attitude by requiring specific standards with respect to pain relieving drugs.

The Animal Studies Committee, as constituted in the bill, would provide valuable assistance to the U.S. Department of Agriculture through its semi annual inspections of the animals.

People for the Ethical Treatment of Animals recommends prompt, favorable action on S. 657.

Statement of Marjorie Anchel, Ph. D., President, New York State Humane Association, New York, N.Y.

The New York State Humane Association represents, besides its individual voting members, over twenty-five societies throughout the State.* We urge the prompt enactment of Senator Dole's bill, S657.

The welfare of experimental animals is one of the deep concerns of our Association. Many of our corporate members are animal shelters, and are all too familiar with the detrimental effects of long-term caging on companion animals. S657 would rectify a serious omission in the present Animal Welfare Act, the requirement for adequate exercise for experimental animals.

A second problem with which we are familiar, is the potential for misuse of paralytics. Because an animal given a muscle relaxant cannot express pain or distress, the effects of these agents have been misunderstood. Paralytics have sometimes been used for "euthanasia". All recommendations for euthanasia, including those of the American Veterinary Medical Association, the Canadian Council on Animal Care and the Institute for the Study of Animal Problems, now list paralytics as unacceptable for this purpose. While the use of paralytics in experimental animals, usually in neurological research, is for a different purpose, the same potential for misuse exists. Because the animal cannot express its distress and pain, it is essential that it be under adequate anesthesia whenever paralytic agents are used. It is too easy for the investigator to overlook this. The required assurance in S657, against the use of paralytics without adequate anesthesia, addresses this problem. While it does not mandate the use of adequate general anesthesia, which would be necessary to avoid terror in the animal, it does require that failure to use general anesthesia be justified, since the award proposal must include "in the justification of the research, the details of any procedure likely to produce pain or distress in an experimental animal * * *". It must demonstrate "that the principal investigator has considered possible alternative methods to any such procedure". These provisions, along with the assurance "against the use of paralytics without adequate anesthesia are essential to ensure that pain and distress will not be caused unnecessarily, due to thoughtlessness or indifference.

The provision of S657 for establishing a service at the National Agricultural Library, to provide information on experimental methods which would reduce or replace the use of animals, or minimize pain and distress, and would prevent unnecessary duplication of animal experimentation, is an important one. It should encourage the use of "alternatives" and reduce the numbers of animals used. Together with the provision for instruction and training in animal care and use, and in the availability of alternative methods, it should be a significant step in the direction of eliminating unnecessary suffering of experimental animals.

One of the most important provisions of the bill, of paramount concern to all humane groups and to all thoughtful persons, is the establishment of an institutional animal studies committee that includes at least one member who "shall not be affiliated with the research facility, and shall be primarily responsible for representing community concerns regarding the welfare of animal subjects". A spokesman for the experimental subject has been found necessary and advantageous in human experimentation, and is obviously even more so when the experimental subjects are animals. No amount of regulation will substitute for the presence of a concerned spokesman, and the humane community will never feel reassured without one. We feel that the inclusion of such a spokesman is an essential part of any attempt to make animal experimentation more humane.

The New York State Humane Association is convinced that many aspects of animal experimentation that are objectionable to the humane community result, not from scientific requirements, but from indifference on the part of some investigators. The provisions of S657 seem to use to address this problem without in any way interfering with the valid needs of scientific research.

*American Fund for Alternatives to Animal Research (and 27 others).

Statement of Robert O. Wagner, Executive Director, American Association of Zoological Parks and Aquariums, Wheeling, W. Va.

The American Association of Zoological Parks and Aquariums (AAZPA) represents virtually every major zoological park, aquarium, wildlife park and oceanarium on the North American continent and the vast majority of the professional staff members employed therein. AAZPA also represents and is the official spokesman for nearly 350,000 members of various zoological park and aquarium support organizations that offer assistance to zoological facilities in their communities. Collectively, zoos and aquariums in this country annually play host to more than 100,000 visitors.

AAZPA was established to aid, foster and engage in the exchange of zoological specimens for exhibiting, conservation, scientific and preservation purposes, cooperating with governmental agencies for the health and welfare of animals and assisting these agencies in the drafting of legislation and regulations; to respect conditions and regulations established by any country in the protection of its animal life in both importation and exportation; and to foster sound captive animal management practices and engender research and study designed to increase biological knowledge and understanding. As is clear from this mission statement, AAZPA acknowledges and respects the public's concern for the protection of domestic and nondomestic animal life.

We support the intent of S. 657 to protect the welfare of animals and to ensure humane treatment, care and appropriate use of laboratory animals. We also believe in the utilization of alternative methods, where possible, to the use of live animals in research and testing.

We have met with your staff and it is our understanding that the majority of activities conducted by zoological facilities are not covered by S. 657. Therefore, we would like to go on record to clarify the status of those activities. In addition, we would request that the attached language be included in the Committee's report on S. 657.

The focus of our concern is that the Animal Welfare Act would be amended to now include zoological facilities as research facilities in all cases. Zoological facilities are licensed as exhibitors, and thus are inspected by USDA to insure compliance with the standards of the Animal Welfare Act. Independently, the Animal Welfare Act also requires registration and inspection of research facilities.

This concern is founded on the lack of a definition for the term "research" and on the definition of "federal award" which includes cooperative agreements, loans and contracts. We understand that it is not the intent of S. 657 to broaden the term research facility to include zoological institutions unless they receive federal funding to conduct specific research as part of a federal grant or unless they are already classified by the Animal and Plant Health Inspection Service as research facilities as well as exhibitors.

We also understand that the permitting systems established by the Marine Mammal Protection Act, the Endangered Species Act and the Migratory Bird Treaty Act are not intended to be covered by this Act. Zoological institutions already comply with humane care, handling, and transportation regulations promulgated pursuant to these statutes.

Many zoological institutions receive Federal awards without the provision of specific federal funding, such as cooperative agreements, loans and contracts. The majority of these awards are initiated by Federal authorities for the purpose of placing confiscated, beached, stranded, sick, injured or orphaned wildlife under the professional care of a zoological institution and its staff. We understand that such activities are not intended to be included as Federal awards, and therefore are not covered by S. 657.

Finally, the term "direct use of conscious animals" is not intended to include routine treatment and preventative medicine programs used in regular veterinary care and reproductive husbandry techniques.

One area of concern which remains is the provision of the bill which would change the standards of animal care from "minimum" to "proper". The "proper" standards would have to be developed for each species covered by the Act. We are concerned because that would be extremely cumbersome, time consuming and costly. At present, the Animal and plant Health Inspection Service does not have sufficient funds to adequately administer those programs and regulations over which it already has control. This would be an added burden. More importantly, we are unsure what the term "proper" means.

We thank you for the opportunity to submit these comments for the record. We believe that our clarifications will distinguish between laboratory facilities and the efforts of zoological institutions to provide sanctuary to wildlife. It should be noted that the primary research conducted by the zoological community on wildlife is intended to enhance the health, propagation, survival or conservation of all wildlife.

We will be pleased to work with you, your staff, or members of your committee in any way. Please do not hesitate to call upon us.

STATEMENT OF MARY C. WARNER, PRESIDENT, ACTION 81 INC., BERRYVILLE, VA.

S. 657, Senator Robert Dole's laboratory animal bill, would provide a public member on the Animal Studies Committee to represent public concerns for the laboratory animals.

It would protect laboratory workers who report mistreatment of the animals.

Dog and cat owners throughout the United States are victims of organized pet theft. There are strong indications that many of these animals are ending up in research laboratories.

The laboratory technicians who receive the animals are often aware that some are privately owned pets. Fear of job loss may prevent action on their part.

Action 81, Inc, a private foundation chartered in VA and operating since 1976 as a national network to expose and prevent pet theft, has recently conducted a random survey on the problem of "vanishing dogs and cats."

Humane agencies in 39 states reported the problem as "serious."

A Rochester, N.Y. Police Sergeant reported "over 10,000 dogs missing-stolen within approximately a 6-month period, with a property value of over $1,500,000 loss to the residents of N.Y. . . ."

An Action 81 contact in Wisconsin stated that occupants of a green pickup had been seen taking a dog, changing license plates, and then selling the dogs to a nearby University Hospital. Reports of this type of activity are common throughout the country.

At another University Hospital a laboratory technician was greatly concerned about the incoming shipments of cats. Many wore collars with bells, flea collars, and others had been de-clawed, spayed, or neutered. The laboratory supervisor's response to the situation was to call the dealer and tell him to "take the ——— collars off."

The technician was too afraid of losing his job to report it further.

In April, 1982, a Siberian Husky with a tattoo was found by its owner in the Eastern Virginia Medical Authority Laboratory in Norfolk, Va. Someone at the Norfolk Pound, which sent the dog to the laboratory, tipped off the owner. The dog had been at the laboratory for several weeks and showed signs of experiments.

A New Jersey licensed federal dealer was arrested in February, 1983, and charged with violations of the Animal Welfare Act. At least one stolen dog was reported in the overcrowded van and several "missing dogs."

In March 1981, a bill was passed in Virginia which banned the sale of pound animals to out of state dealers. Theft and unexplained "disappearances" of privately owned dogs comprised the single issue. More than 8,000 missing dogs from one-seventh of VA had been reported in 1980 to Action 81, with a combined estimated loss to their owners of $1,500,000.

Since passage of this bill the Action 81 missing dog statistics have decreased by nearly 50 percent in Virginia. Sign of human involvement in the disappearances continue. Approx. 60 percent are purebred.

The contract system of procurement of research dogs and cats opens the door to theft of private property. The contracts with the dealers often call for specified numbers, breeds, sizes, and dates for delivery. Tractable, healthy purebreds are preferred in most instances.

A trial involving a Chase City, VA, licensed Federal dealer was held June 29. Lack of identification and records were among the U.S.D.A. charges. To quote the dealer's assistant at the trial, "We don't take the sick or mean dogs!"

Pressure on the dealers to obtain the required animals as stated in the contracts can result in stolen animals being added to a legitimate collection by unscrupulous persons for profit

Theft of dogs and cats is so widespread in North Carolina that a State Animal Theft Committee has been formed. Larceny of both dogs and cats is now a felony. Efforts are strong to close the pounds to all dealers.

Dogs and cats are hauled long distances and across many state lines, making it difficult for owners to recover missing or stolen pets.

A prominent licensed federal dealer from Quakertown, Pa,, was recently arrested in Rolla, Missouri for cruelty. The dealer was on a routine trip through the midwest to collect dogs. Tractor trailers from the east have been sighted hauling dogs in Montana where pet theft is high.

Senator Dole's bill, S. 657, would alleviate the present situation.

The public member on the Animal Studies Committee would be able to represent public concerns about the animals, including the acquisition of citizens' pets.

The bill would protect any laboratory worker reporting the mistreatment of animals, and, as in the case of the cats with the bell collars, the procurement and presence in the laboratory of privately owned dogs and cats.

STATEMENT OF DR. CONNIE KAGAN, NATIONAL ALLIANCE FOR ANIMAL LEGISLATION

The National Alliance for Animal Legislation is pleased to submit this statement about proposed legislation regarding animals used in research and testing.

The legislation is a progressive step in addressing a serious and costly situation. Approximately 70 million animals—including primates, dogs, cats, rabbits, and other species—are used each year in federally-funded experiments at a cost of approximately 3 billion dollars. Clearly, there is both a humane concern and a concern about the use of limited federal resources. This legislation addresses both these concerns.

The standards for care provide for some basic improvements in the situation of animals in laboratories. These improvements would not only benefit the animals, they would also be cost-effective in two ways: (1) reducing the need to replace animals who become ill or die and (2) reducing the possibility of invalid findings as a result of uncontrolled variables due to the animals' stress and/or illness.

The requirement for a functioning Animal Studies Committee, including a veterinarian and a member charged with representing community concerns regarding the welfare of the animals, is an appropriate means of strengthening internal monitoring and accountability for the use of animals and the use of federal funds. The inclusion of a veterinarian addresses the need for technical expertise regarding animal care. The inclusion of an outside member charged with representing community concerns regarding the welfare of animal subjects addresses the need for animal protection and reflects societal and moral concerns.

The Animal Studies Committee, as a monitoring mechanism, is non-intrusive and emphasizing the expectation that institutions will act responsibly with regard to animals and with regard to the use of federal funds. USDA/APHIS and HIH have documented cases of serious abuse of animals and long-standing violations of the Animal Welfare Act by federally-funded institutions. Whether the Animal Studies Committee will be sufficient means for assuring institutional responsibility remains to be seen, but it is an appropriate step.

The requirement to establish an information service at the National Agricultural Library is an obvious and necessary means: (1) to reduce the use of animals; (2) to reduce the waste of federal funds on unnecessary replication; (3) to increase the usefulness of research by making findings easily accessible.

The requirement that each proposal for using animals must show a consideration of alternatives and, if animals are used, assurances of basic veterinary medical care for them is an appropriate means of emphasizing individual responsibility for animals and for careful use of federal funds.

In summary, the provisions of this legislation are progressive steps in addressing concerns about animal protection and concerns about careful use of federal funds.

A remaining question is whether or not these concerns must be addressed by legislation rather than by administrative or professional regulations.

As a practical matter, these concerns have not been adequately addressed by self-regulation in the past, and there is no evidence to suggest that they are more likely to be now.

More importantly, what is needed is accountability and legislation, as opposed to self-regulation, obviously increases accountability. To break the law is a very different matter from not conforming to a regulation or disappointing one's peers.

Furthermore, since failure to act responsibly with regard to animals harms the animals, the paternalism principle of constitutional law is relevant. Since animals are a class of individuals who have special vulnerability in that they cannot protect themselves, the paternalism principle justifies special intervention, in this case, legislation, to assure more stringent accountability for their treatment.

II

98TH CONGRESS
1ST SESSION

S. 657

To amend the Animal Welfare Act to ensure the proper treatment of laboratory animals.

IN THE SENATE OF THE UNITED STATES

MARCH 2 (legislative day, FEBRUARY 23), 1983

Mr. DOLE (for himself, Mr. MELCHER, Mr. RANDOLPH, Mr. HEINZ, Mr. PERCY, and Mr. STEVENS) introduced the following bill; which was read twice and referred to the Committee on Agriculture, Nutrition, and Forestry

A BILL

To amend the Animal Welfare Act to ensure the proper treatment of laboratory animals.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SHORT TITLE

SECTION 1. This Act may be cited as the "Improved Standards for Laboratory Animals Act".

FINDINGS

SEC. 2. The Congress finds that—

(1) methods of testing that do not use animals have been developed which show promise of being faster, less expensive, and more accurate than tradi-

tional animal experiments for some purposes and further opportunities exist for the development of these methods of testing;

(2) measures which eliminate or minimize the unnecessary duplication of experiments on animals can result in more productive use of Federal funds; and

(3) measures which help meet the public concern for laboratory animal care and treatment are important in assuring that research will continue to progress.

DEFINITIONS

SEC. 3. (a) Section 2(e) of the Animal Welfare Act (7 U.S.C. 2132(e)) is amended by adding after "The term 'research facility' means" the following: "each department, agency, or instrumentality of the United States which uses animals for research or experimentation,".

(b)(1) Subsections (f), (g), (h), (i), and (j) are redesignated as subsections (j), (k), (l), (m), and (n), respectively.

(2) Section 2 of the Animal Welfare Act is amended by adding after subsection (e) the following:

"(f) The term 'Federal agency' means an executive agency as such term is defined in section 105 of title 5, United States Code, and with respect to any research facility means the agency from which the research facility has received or may receive a Federal award for the conduct of research, experimentation, or testing, involving the use of animals;

"(g) The term 'Federal award for the conduct of research, experimentation, or testing, involving the use of animals' means any mechanism (grant, contract, cooperative agreement, or loan) under which Federal funds are provided to support the conduct of such research;

"(h) The term 'direct use of conscious animals' means any use or procedure that involves more than momentary minor pain or discomfort, except where the animal is anesthetized throughout the entire course of that use or procedure;

"(i) The term 'quorum' means a majority of the committee members;".

STANDARDS AND CERTIFICATION PROCESS

SEC. 4. (a) Subsection (a) of section 13 of the Animal Welfare Act is amended by adding after "(a)" the following: "(1)".

(b) The second sentence of section 13(a) of the Animal Welfare Act (7 U.S.C. 2143(a)) is amended to read as follows: "Such standards shall include—

"(A) proper requirements with respect to handling, housing, feeding, watering, sanitation, ventilation, and shelter from extremes of weather and temperatures;

"(B) provision for adequate exercise and separation by species where the Secretary finds that such separation is necessary for humane handling; and

"(C) provision for adequate veterinary care, including the appropriate use of anesthetic, analgesic, or tranquilizing drugs and appropriate presurgical and post-surgical medical and nursing care.".

(c) The last sentence of section 13(a) of the Animal Welfare Act (7 U.S.C. 2143(a)) is amended to read as follows: "Nothing in this Act shall be construed as authorizing the Secretary to promulgate rules, regulations, or orders with regard to design of research or experimentation by a research facility. The Secretary shall promulgate standards for research facilities, including proper requirements for animal care, treatment, and methodology in experimental procedures to ensure that animal pain and distress are minimized. The Secretary shall require, at least annually, every research facility to show that the standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs during experimentation, are being followed by the research facility during research and experimentation.".

(d) Subsection (a) of section 13 of the Animal Welfare Act is amended by adding at the end thereof the following:

"(2)(A) The Secretary shall require that each research facility establish an institutional animal studies committee (hereinafter in this paragraph referred to as the 'committee') composed of not fewer than three members. Such members shall possess sufficient expertise to assess the appropriateness of animal care and treatment in experimental research. Of the members of the committee—

"(i) at least one member shall be a doctor of veterinary medicine;

"(ii) at least one member shall not be affiliated with the research facility and shall be primarily responsible for representing community concerns regarding the welfare of animal subjects (such member shall provide adequate assurances that he or she will not release any trade secrets or confidential information of the research facility); and

"(iii) not more than three members, in those cases where the committee consists of more than three members, shall be from the same administrative unit of the research facility.

"(B) Such committee shall—

"(i) meet regularly with a quorum for all formal actions;

"(ii) make inspections at least semiannually of all animal study areas and facilities of the research facility;

"(iii) review as part of the inspection of the research facility the research methods and practices involving direct use of conscious animals and the condition of research animals for the purpose of evaluating those research methods and practices to ensure that animal pain and distress are minimized and to ensure compliance with the standards for appropriate animal care, treatment, and methodology; and

"(iv) file with the Secretary and with any Federal agency from which the research facility is receiving an award, a certification that such semiannual inspections and reviews have taken place.

The inspection certification required by subparagraph (B)(iv) shall include reports of any violations of standards promulgated by the Secretary, deficient conditions of animal care or treatment, and deviations of research methods and practices from originally approved proposals that adversely affect animal welfare. Such inspection certification shall be signed by a majority of the committee members. The committee shall file complete records of their inspection certification visits (including attendance of committee members) and other information pertinent to its activities. Any minority views shall be included in the certification records. Such records shall be maintained for at least three years by the committee or the research facility and available for inspection by any appropriate Federal agency.

"(C) The committee shall notify the Animal and Plant Health Inspection Service of the Department of Agriculture and any Federal agency from which the research facility is receiving an award, in writing, of any unacceptable conditions of animal care, treatment, or methodology which have not been included in the certification. The notification shall be made only after the administrative representative of the research facility has been notified by the committee of the unacceptable conditions and the research facility is given an opportunity to make such conditions acceptable.

"(D) The committee shall provide for annual sessions for scientists, animal technicians, and other personnel involved with animal care and treatment in research facilities, which provide instruction or training in—

"(i) the humane practice of animal maintenance and experimentation;

"(ii) the concept, availability, and use of research or testing methods that minimize or eliminate the use of animals or limit animal pain or distress; and

"(iii) utilization of the information service at the National Agricultural Library established under subsection (e) to prevent unnecessary duplication of animal experimentation by research facilities.

"(3) Research facilities shall inform their employees of the provisions of this section and shall inform such employees to report to the committee any violations of such provisions. Employees of such facilities may not be discriminated against because such employees reported any such violation.

"(4) The Secretary may waive the standards established under this section under exceptional circumstances which are related to the needs for research results or special and unusual circumstances of the research facility.".

(e) Section 13 of the Animal Welfare Act is amended by adding at the end thereof the following:

"(e) The Secretary shall facilitate agency compliance with the requirements of this section through the establishment of an information service at the National Agricultural Library. The National Agricultural Library shall, in cooperation with the National Library of Medicine, provide information on improved methods of animal experimentation including methods which would—

"(1) reduce or replace animal use;

"(2) minimize pain and distress, such as anesthetic and analgesic procedures; and

"(3) prevent unnecessary duplication of animal experimentation.

"(f)(1) A research facility shall provide a statement of assurance of compliance with this section upon requesting a Federal award for the conduct of research, experimentation, or testing involving the use of animals to the Secretary of Agriculture and to the Secretary of any Federal agency from which such research facility is requesting such award.

"(2) No Federal agency may approve any research facility for the receipt of a Federal award for the conduct of research, experimentation, or testing unless the agency finds, as a result of its review of the scientific merit of the proposal, that the award proposal includes—

"(A) in its justification of the research, the details of any procedure likely to produce pain or distress in an experimental animal and demonstrates that the principal investigator has considered possible alternative methods to any such procedure;

"(B) in any case involving the direct use of conscious animals, appropriate assurances that a doctor of veterinary medicine has been consulted in the planning of such procedures;

"(C) in any case involving the direct use of conscious animals, assurances—

"(i) for the proper use of tranquilizers, analgesics, and anesthetics;

"(ii) for appropriate presurgical and postsurgical medical and nursing care;

"(iii) against use of paralytics without adequate anesthesia; and

"(iv) that the withholding of tranquilizers, anesthesia, analgesia, or euthanasia when scientifically necessary shall continue for only the necessary period of time; and

"(D) except in cases of scientific necessity or other special circumstances as determined by the animal studies committee, assurances that no animal may be used in more than one major operative procedure from which it is allowed to recover.

"(g) The Secretary of Agriculture shall promulgate standards for compliance with this section. In any case in which the sponsoring Federal agency determines that conditions of animal care, treatment, or methodology in a particular project have not been in compliance with applicable standards, despite notification to the research facility, that agency shall suspend or revoke Federal support for the project. Any research facility losing Federal support as a result of actions taken under the preceding sentence shall have the right of appeal as provided in sections 701 through 706 of title 5, United States Code.".

EFFECTIVE DATE

SEC. 5. This Act shall take effect one year after the date of enactment.

DEPARTMENT OF AGRICULTURE,
OFFICE OF THE SECRETARY,
Washington, D.C., October 12, 1983.

Hon. JESSE HELMS,
Chairman, Committee on Agriculture, Nutrition, and Forestry,
U.S. Senate,
Washington, D.C.

DEAR MR. CHAIRMAN: This is in response to your request for a report on S. 657, a bill "To amend the Animal Welfare Act to ensure the proper treatment of laboratory animals," cited as the "Improved Standards for Laboratory Animals Act."

The Department opposes enactment of this bill. However, the Department wishes to be on record as strongly supporting humane care and treatment of animals used for purposes of biomedical research.

The bill amends the Animal Welfare Act as follows:

(1) Expands the definition of the term "research facility" to include each department, agency or instrumentality of the United States which uses animals for research or experimentation.

(2) Defines the term "Federal agency" to mean any Executive agency from which the research facility has received or may receive Federal funds to support the conduct of research, experimentation, or testing involving the use of animals. Federal support can be revoked or suspended for continued failure to comply with the standards of animal care, treatment, or methodology to be promulgated by the Secretary of Agriculture. These standards can be waived by the Secretary under exceptional circumstances related to the needs for research results or special and unusual circumstances of the research facility.

(3) Defines the term "direct use of conscious animals" to mean any use or procedure that involves more than momentary minor pain or discomfort, except where the animal is anesthetized throughout the entire course of that use or procedure. Requires the Secretary of Agriculture to promulgate standards to ensure that animal pain and distress are minimized. Also requires the the Secretary to promulgate "proper" instead of "minimum" standards to govern humane handling, care, treatment, and transportation of animals by dealers, research facilities, and exhibitors; adds "adequate exercise" as a standard; and, expands the standard for adequate veterinary care to include appropriate presurgical and post-surgical medical and nursing care.

(4) Repeals the prohibition against the the Secretary regulating outlines, guidelines or performance of actual research or experimentation by a research facility.

(5) Mandates the establishment and makeup of an institutional animal studies committee of three or more members within each research facility. The committee must make inspections at least semiannually of all animal study areas and facilities of the research facility. A certification must be filed with the the Secretary of Agriculture and any Federal agency from which the research facility is receiving an award that the inspections took place. The Department of Agriculture's Animal and Plant Health Inspection Service must be notified, in writing, of any unacceptable conditions of animal care, treatment, or methodology which were not included in the inspection certification. Also, the committee must provide for annual sessions of instruction or training in humane practices and research methods for scientists, animal technicians, and other personnel involved with animal care and treatment in research facilities.

(6) Requires each research facility, when requesting a Federal award to provide the Secretary of Agriculture and the Secretary of any Federal agency from which the award is requested, with a statement of assurance of compliance with the standards of animal care, treatment, or methodology.

(7) Mandates the establishment of an information service on improved methods of animal experimentation at the National Agricultural Library to facilitate agency compliance with the standards.

The Department, through the Animal and Plant Health Inspection Service [APHIS], administers the Animal Welfare Act. APHIS is responsible for the registration and inspection of approximately 3,300 State-owned and privately owned research facilities in the United States. While Federal laboratories are not required to register with APHIS, they are required to comply with the same standards of care and treatment and reporting requirements established for State-owned and privately owned research facilities. Federal agencies, through internal systems, monitor compliance of Federal laboratories. Therefore, we question the need to expand the definition of "research facility" to include Federal laboratories.

We do not feel that "pain" can be measured objectively. Determination as to whether an animal is suffering momentary pain or discomfort during actual research or experimentation should be a required element of professional judgment made by the trained doctors of veterinary medicine in charge of the research and researchers trained in other biomedical sciences. Therefore, we object to the bill's definition of the term "direct use of conscious animals" which would require the Secretary of Agriculture to promulgate regulations establishing standards for momentary minor pain and discomfort for various animal species.

We do not concur in changing standards of care and treatment from "minimum" to "proper" because the term "minimum" is more definitive, and therefore, more enforceable in a court of law. In practice, requirements for proper care and treatment of animals used for purposes of research, exhibition, transportation, etc., can be met under current authorities.

Also, we do not favor adding "adequate exercise" as a required standard because it would be extremely difficult to determine what is "adequate" for the various species and number of animals that would be involved. Our regulations require that the primary enclosure for each animal be constructed and maintained to allow the animal "adequate" space for freedom of movement in all directions. In addition, our inspectors are required to pay special attention to animals kept in small enclosures to ensure that the space provided meets our requirements, unless the research protocol calls for restricted space.

The bill repeals the prohibition against the Secretary of Agriculture regulating outlines, guidelines or performance of actual research or experimentation by a research facility. Repeal of this prohibition, coupled with the requirement that the Secretary promulgate standards to ensure that animal pain and distress are minimized, would place the Secretary of Agriculture in the position of regulating research projects of other Federal agencies.

The requirement that the institutional animal studies committee provide the Secretary of Agriculture with semiannual reports certifying that inspections of research facilities took place would necessitate an increase in clerical and technical staff. Review of the semiannual reports, the notifications of unacceptable conditions, and the statements of assurances, in addition to the currently required annual report of research facilities, and the inspection reports would be time-consuming and would not necessarily achieve the important goals of providing proper care and treatment of laboratory animals.

Increased public interest in the humane care and treatment of laboratory animals prompted the Department to do an in-depth review of its enforcement of the Animal Welfare Act as it relates to research facilities. The review was directed toward determining whether inspection operations provided adequate assurances that laboratory animals are receiving appropriate care and treatment. As a result, we revised a number of our internal policy memoranda to provide more specific and uniform instructions for the veterinarians who actually conduct the inspections. Detailed written instructions have been developed on how to conduct inspections. To assure quality of inspections, we have established annual training sessions and intermediate training where needed, for all animal care personnel. Video tapes, slide presentations, and inspection workshops are used to reinforce the written instructions. Also, the Area Veterinarian-in-Charge (AVIC) has been made primarily responsible for the assignment of properly trained and committed animal care personnel considered to be capable of successfully implementing our authorities under the Animal Welfare Act.

The establishment of an information system on improved methods of animal experimentation at the National Agricultural Library (NAL) can be achieved under current authorities. Presently, the NAL provides basic level services in support of programs within the Department. These services include collecting and indexing the leading publications in a particular field, document delivery, general reference, current awareness, and computerized bibliographies. Thus, with relatively little additional effort, NAL could expand these services to include animal experimentation.

Clearly, the bill greatly increases the Department's responsibilities under the Act and would require substantial expansion of our animal care enforcement program to which we have already fully extended available resources and manpower. We believe that our common goals of ensuring proper care and treatment and appropriate use of laboratory animals can be achieved under current authorities. Therefore, we do not recommend enactment of the bill.

The Office of Management and Budget advises that there is no objection to the presentation of this report from the standpoint of the Administration's program.

Sincerely,

JOHN R. BLOCK, *Secretary.*

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